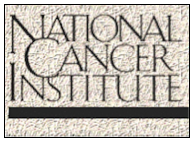

CANCER THERAPY EVALUATION PROGRAM, NATIONAL CANCER INSTITUTE

Adverse Event Expedited Reporting System (AdEERS)

VERSION 2.0 - JULY 17, 2000

APPLICATION USER'S GUIDE

PRODUCED BY CAPITAL TECHNOLOGY INFORMATION SERVICES, INC.

The Adverse Event Expedited Reporting System (AdEERS) was prepared for:

Cancer Therapy Evaluation Program (CTEP)

Division of Cancer Treatment and Diagnosis

National Cancer Institute (NCI)

National Institutes of Health (NIH)

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The date on the cover of this user's guide reflects the document release date, which may differ from the software release date.

Information within this user's guide is current as of the date of publication. Software changes and enhancements incorporated into the system after the publication date will be reflected in future releases of the guide.

Contents

Before You Begin

Introduction

The Adverse Event Expedited Reporting System (AdEERS) is a Web-based computer application used to electronically submit Expedited Reports for events experienced with investigational agents supplied by the National Cancer Institute (NCI) Division of Cancer Treatment and Diagnosis (DCTD). AdEERS is designed to support the classification, retrieval, and evaluation of Adverse Event information. The goal of AdEERS is to minimize over-reporting and increase the efficiency, completeness, and accuracy of safety monitoring and reporting to the Food and Drug Administration. AdEERS presents a series of screens with open windows in which the user enters information needed to create and submit an Expedited Report.

An Adverse Event is any unfavorable or unintended symptom, sign, or disease that may or may not be considered related to the intervention. The National Cancer Institute (NCI) Common Toxicity Criteria, Version 2.0 (CTC v2.0) is the standard language for reporting Adverse Events. The CTC includes criteria for reporting severity using a grading scale of 1 through 5. NCI Expedited Reporting requirements are based on the phase of the trial, the CTC v2.0 Adverse Event, the grade of the event, and the attribution.

In 1997, the International Conference on Harmonization addressed the development of a single medical terminology, Medical Dictionary for Drug Regulatory Affairs (MedDRA), for regulatory reporting globally. To facilitate data transfer to the FDA and other regulatory agencies, NCI incorporated wherever possible, mapping to preferred terms of MedDRA. In AdEERS, lists of values mapped to MedDRA include:

- Adverse Event Terms,
- Disease Names,
- Prior Therapies, and
- Pre-Existing Conditions.

If you have any comments or questions regarding this User's Guide, please contact the NCI CTEP Help Desk by telephone at (301) 840-8202, fax (301) 948-2242, or E-mail at http://ncictephelp.ctep.info.nih.gov.

What this Guide Provides

This guide provides comprehensive instructions on how to use AdEERS. Step-by-step instructions are provided for each procedure that is performed using AdEERS to submit Expedited Reports.

User Guide Conventions

The command names, Dialog Box names, data element names, and menu names appear in **Bold** text.

Text that appears in *italics* on the screen will be shown in *italics* in the user guide.

The following terms are defined as follows:

- Click indicates that the mouse pointer is moved to a specified item and the left mouse button is pressed once.
- Select indicates the user highlights an item in a list or picks an option from a group of options by clicking the option.

AdEERS Conventions

In addition to moving through the AdEERS screens using the AdEERS menu and commands, the screens may be navigated by using the Previous or Next commands provided by the browser. Some AdEERS screens are divided into several windows. Window size may be adjusted by dragging the window dividers in the desired direction. Some windows have scroll bars that allow viewing of unseen portions of the window.

Bold and Italics

On any AdEERS screen, requested information shown in **bold** text is categorized as mandatory data, and must be entered to save a screen and submit an Expedited Report. Information shown in *italics* is categorized as required information if available and/or appropriate for the patient. To enter any information requested, click the adjacent text box and then type.

On-Screen Buttons

Save must be used before leaving any screen; otherwise any new information entered will be lost. If any mandatory data (requested information in **bold** text) is missing when **Save** is clicked, an "Error" message appears followed by a prompt to provide the requested information. A "Success" message appears whenever the information entered has been successfully saved.

ReQuery refreshes the list of records saved for a section (screen). **ReQuery** allows review of data entered.

Clear clears data fields if the section (screen) has not been saved.

Close closes the window or Dialog Box without making any selections or changes.

Delete deletes data fields after the section (screen) has been saved. Click the record to be deleted; click **Delete**; "Confirm the delete" message appears; click **Yes**; click **ReQuery** to view that the deleted record is gone.

New is clicked to begin entering data on a "new" screen.

Entering Dates

Unless otherwise noted, dates are entered in the format MM/DD/YYYY, which means Month/Day/Year, where month and day must be two digits, and year must be four digits. For example, January 4, 2000 would be entered as 01/04/2000. The Calendar icon may also be used to enter dates.

Drop Down Lists

Some text boxes have drop down arrow buttons directly attached to the text box that provide a drop down list of values that are valid for the text box.

Lists of Values

Some text boxes have drop down arrow buttons next to them, but not attached to the text box, that provide access to a list of alternative values. Click the arrow and a **List Of Values** (LOV) appears with a list of the values from which to choose.

One method of locating the desired item in the LOV is to use the scroll bar located on the right side of the list.

After a **List Of Values** appears, the length of the LOV can be further reduced. To do this, identifying information is entered into the **Search Criterion** text box and then **Find** is clicked. This simplifies finding the desired information. When the desired value is located and selected, it is automatically inserted into the requested information text box.

Because some LOVs are lengthy, a search feature using the wildcard **%** is provided to reduce the size of the LOV. To assure the most accurate LOV for the term searched, type **%** followed by a key word, and then another **%**. The search engine is not case sensitive. Thus, both upper and lowercase characters are acceptable. The following list provides a sample of returns in the Disease LOV for various search strings looking for lung cancer:

- **%**L — no return
- L**%** — Lip and/or oral cavity cancer NOS
Lymphoma AIDS-related
Large cell lung cancer NOS
Laryngeal cancer
- Lung**%** — no return
- **%**lung**%** — Large cell lung cancer NOS
Non-small cell lung cancer NOS
Small cell lung cancer stage unspecified

The only search string that returns all possibilities for lung cancer is **%**lung**%**.

The following is an example of a **List of Values**:

Figure 1 - List of Values

Getting Help

AdEERS provides several methods to assist in working through questions.

The first method is the on-line help, accessed by clicking the Help Icon shown below.

The second method is the error messages provided to notify of an issue with the function just performed. Information within the error message helps to isolate and correct the issue.

The third method is to review this user guide. Specific instructions are provided for each function of AdEERS.

The fourth method is to contact the NCI CTEP Help Desk by telephone (301) 840-8202, fax (301) 948-2242 or E-mail at http://ncictephelp.ctep.info.nih.gov.

System Requirements

AdEERS runs on the MS Windows 95 or 98 operating system. To run the system, the following is needed:

- An IBM®-compatible personal computer with an 80486sx, 80486, or higher processor (80486/20 or higher recommended).
- A hard disk with 10 megabytes (MB) of free space.
- Eight MB of random-access memory (RAM); 16 MB or more recommended.
- A Microsoft Mouse or other compatible pointing device.
- An EGA, VGA, or compatible display—VGA or higher recommended.
- Microsoft Windows 95 or 98.

- A modem fully installed and compatible with Microsoft Windows.
- An Internet Service Provider (ISP).
- A browser such as Internet Explorer 4.0 or Netscape Communicator 4.0.

Note: Netscape Communicator is the preferred browser for AdEERS.

- Acrobat Reader/Adobe Acrobat Reader.

Further Information

Refer to the following resources for additional information.

- NCI CTEP Home Page: http://ctep.info.nih.gov.
- NCI CTEP Common Toxicity Criteria , Version 2.0 (CTC, v2.0) document.
- NCI CTEP Common Toxicity Criteria (CTC) Manual.
- NCI CTEP Common Toxicity Criteria, Version 2.0 (CTC, v2.0) - Notice of Modifications.
- NCI CTEP Clinical Data Update System (CDUS) Instructions and Guidelines.
- NCI Guidelines: Expedited Adverse Event Reporting Requirements for NCI Investigational Agents.
- CTC Interactive Application: https://webapps.ctep.nci.nih.gov/ctcv2/plsql/ctc000w$.startup.
- AdEERS Computer Based Training (CBT): http://ctep.info.nih.gov/AdEERS/default.htm.

To obtain further information, please contact the NCI CTEP Help Desk by telephone at (301) 840-8202, fax (301) 948-2242, or E-mail at http://ncictephelp.ctep.info.nih.gov.

Expedited Adverse Event Reporting System Overview

Overview

The Adverse Event Reporting System (AdEERS) is an online submission point for Expedited Reports occurring on Clinical Trials with NCI-sponsored investigational agents. To facilitate reporting of AE(s) related to commercial agents, a link to the FDA's MedWatch site is provided. A username and password are required to log onto AdEERS. Expedited Reports for NCI-sponsored investigational agents cannot be created without a username and password. Contact your UMS System Administrator to obtain a username and password. To identify the appropriate UMS System Administrator, contact the NCI CTEP Help Desk by telephone at (301) 840-8202, fax (301) 948-2242, or E-mail at http://ncictephelp.ctep.info.nih.gov.

Individuals interested in obtaining a further understanding of AdEERS should review the documents mentioned in the chapter entitled Before You Begin.

AdEERS presents a series of computer screens in which the user selects and enters information needed to submit Expedited Report information. An overview of the AdEERS associated screens is shown in Figure 2.

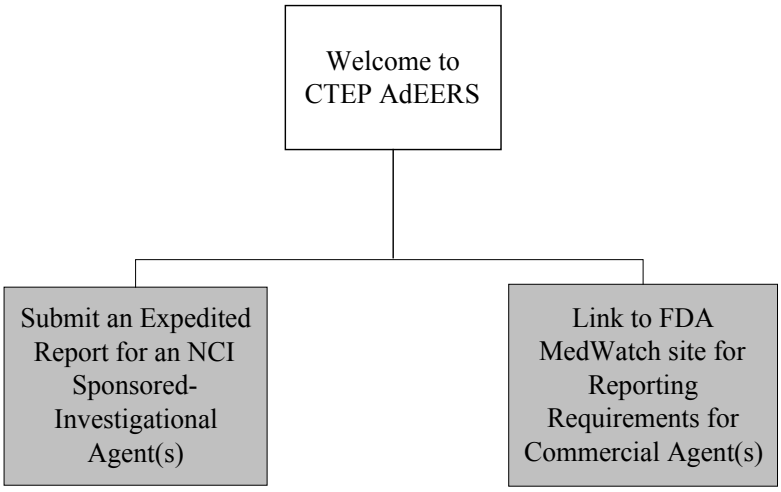

Figure 2 - AdEERS Menu Structure

Logging On

Access to AdEERS can be found on the CTEP Home Page: http://ctep.info.nih.gov/informatics/default.html.

Steps to Log onto AdEERS

1. Open CTEP web site at http://ctep.info.nih.gov.
2. Select the **AdEERS** link or enter the AdEERS URL.

   The **AdEERS** Main Menu appears.

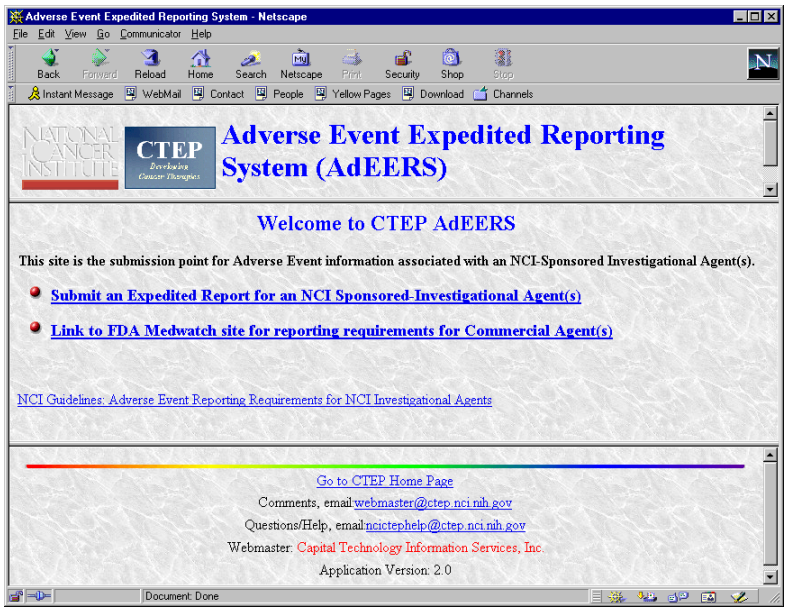

Figure 3 - AdEERS Main Menu - Adverse Event Expedited Reporting System (AdEERS)

3. Click **Submit an Expedited Report for an NCI Sponsored Investigational Agent**.

   The **Username and Password Required** Dialog Box appears.

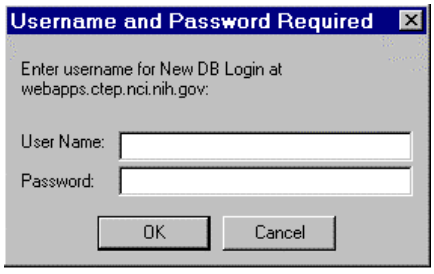

Figure 4 - Username and Password Required Dialog Box

4. Enter username and password provided by the UMS Administrator.

   Access to the options available on the main menu is now available.

The AdEERS Main Menu

The AdEERS Main Menu, shown in Figure 3, is divided into three frames.

1. The top frame provides the name of the screen, **Adverse Event Expedited Reporting System (AdEERS)**.
2. The middle frame, entitled **Welcome to CTEP AdEERS**, provides two menu options to the user:
   - Submit an Expedited Report for an NCI Sponsored Investigational Agent, and
   - Link to FDA MedWatch site For Information Regarding Expedited Reports for Commercial Agents.
   - The middle frame also provides a link for help concerning NCI Guidelines for Expedited Adverse Event Reporting Requirements.
3. The bottom frame provides a web link to the CTEP Home Page, and links for sending email to the CTEP Webmaster or CTEP Help Desk.

Expedited Adverse Event Reporting

Assess Whether or Not an Adverse Event Requires an Expedited Report

AdEERS provides guidelines regarding the reporting requirement for an individual Adverse Event (AE) through a series of screens on which the user provides specific information about the event. This procedure assumes the user has already logged on using the procedure in Steps to Log onto AdEERS on page 8.

1. Select **Submit an Expedited Report for an NCI Sponsored Investigational Agent**.

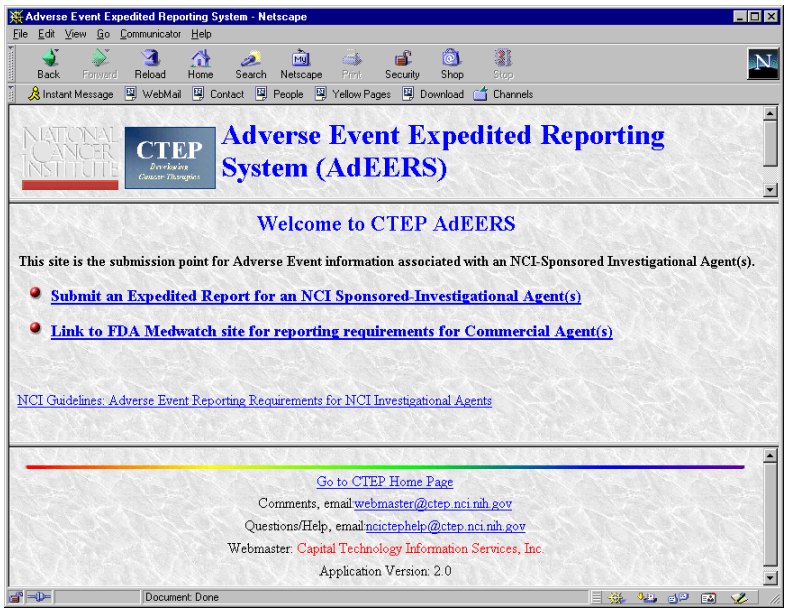

Figure 5 - AdEERS Main Menu - Adverse Event Expedited Reporting System (AdEERS)

After successful logon, a screen appears with a table of protocol(s), specific to the account (username and password) provided at login. Accounts provide one of two roles within the AdEERS application: data entry only; or data entry, attestation, and submission of the report. This table shows the NCI Protocol Numbers and the title of the protocol(s).

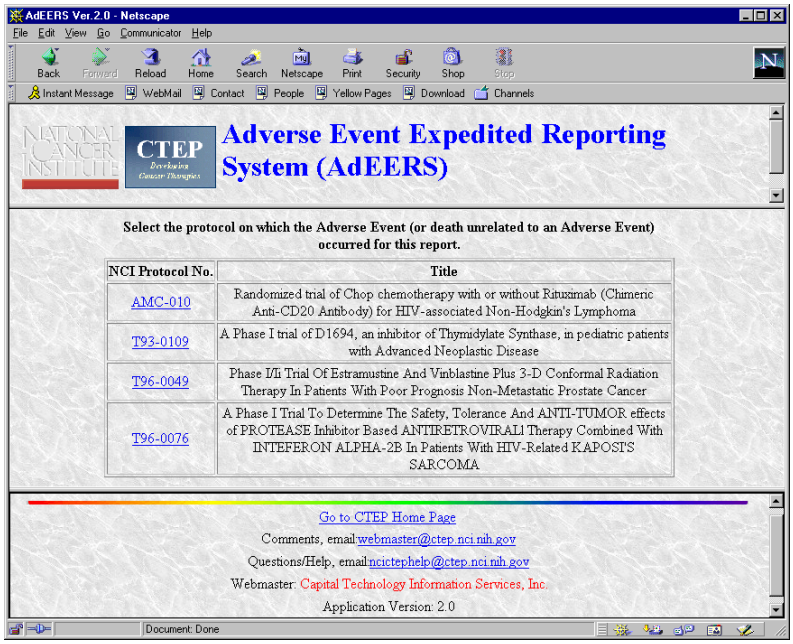

Figure 6 - NCI Protocols Available for Submission of Adverse Event Reports Screen

2. Click the NCI Protocol Number for which an adverse event is to be assessed.

   The **Assess Whether or Not an Adverse Event is Reportable** screen appears, as shown in Figure 7. The following options are available in the left frame of this screen:

   If death is unrelated to an AE, click here – Select to submit an Expedited Report when a death is unrelated to an AE.

   ReQuery – Select to view a list of AE(s) entered for assessment.

   New Adverse Event - Select to begin the check to determine if an AE is reportable.

   Assessment Results - Select to review the reporting requirements for the AE(s) entered.

   Proceed with Report - Select to bypass the assessment and proceed with entering a report.

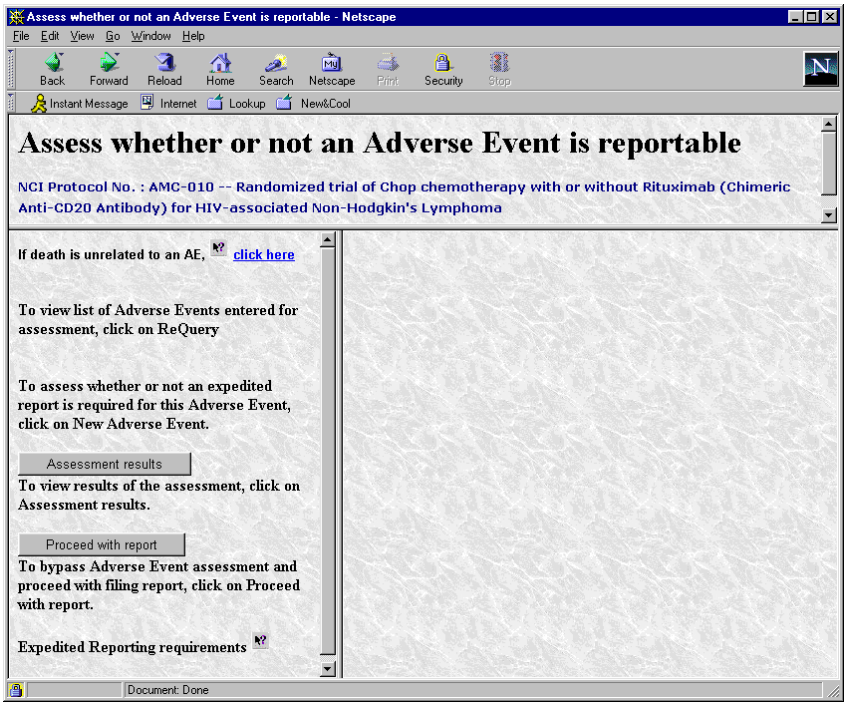

Figure 7 - Assess Whether or Not an Adverse Event is Reportable Screen

3. Click **New Adverse Event**.

   The right frame of the **Assess Whether or Not an Adverse Event is Reportable** screen provides access to CTC for selection of AE(s).

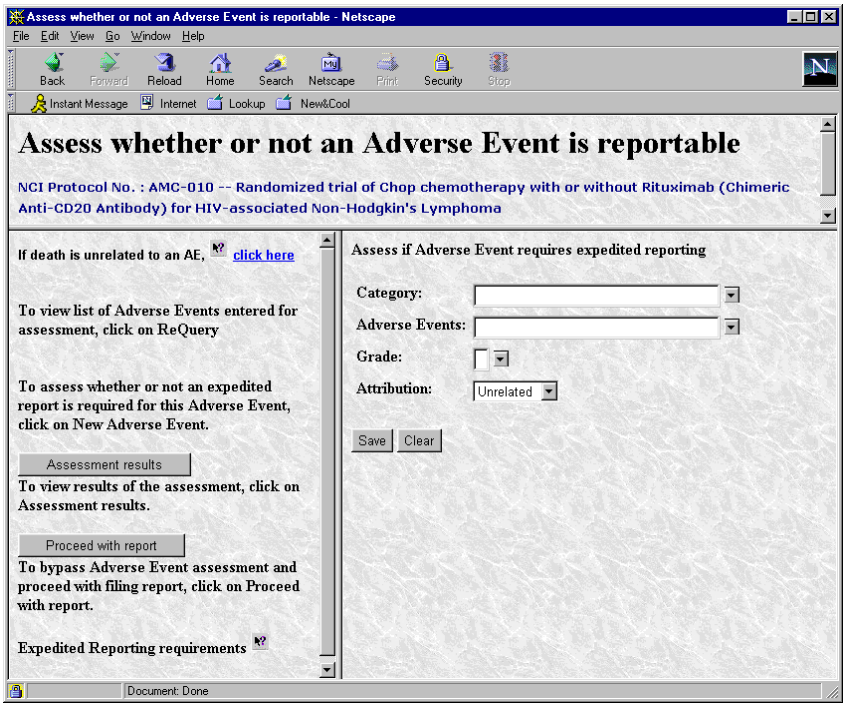

Figure 8 - Check to Assess Whether or Not an Adverse Event is Reportable Screen

4. Click the **CATEGORY:** field down arrow.

The **List Of Values: CATEGORY** appears. This list contains the 24 CATEGORIES of CTC v2.0.

Figure 9 - List Of Values: CATEGORY

5. Select the **CATEGORY**.

   The selected item appears in the **CATEGORY:** field.

6. Click the **Adverse Events:** field down arrow.

   The **List Of Values: Adverse Event** appears for the previously selected CATEGORY with refined values.

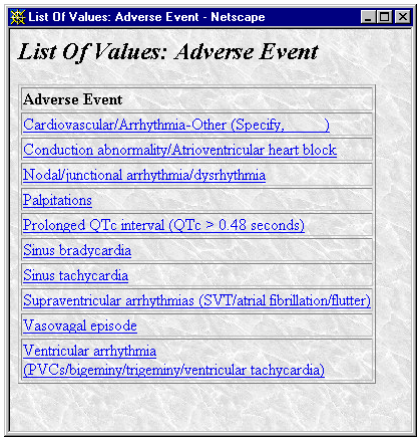

Figure 10 - List Of Values: Adverse Event

7. Select the **Adverse Event**.

   The selected item appears in the **Adverse Events:** field.

8. Click the **Grade:** field down arrow.

The **List Of Values: Grade** appears for the selected AE. The full range of grade values is not applicable to all AE(s). Only the values appropriate for the selected event will be displayed.

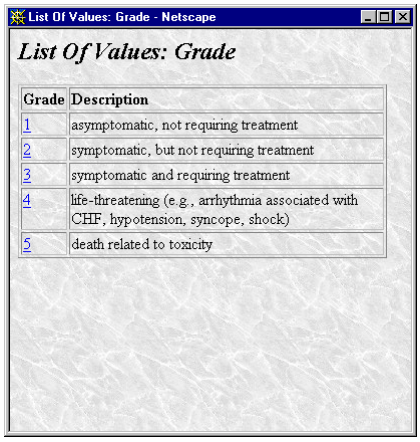

Figure 11 - List Of Values: Grade

9. Select the **Grade**.

   The list of values appears in the **Grade:** field.

10. Click the **Attribution to Investigational Agent:** field down arrow and select one of the available options.

    Attribution is the relationship to agent/intervention. **Unrelated** is the default for this field. The other options are: **Unlikely**, **Possible**, **Probable**, and **Definite**.

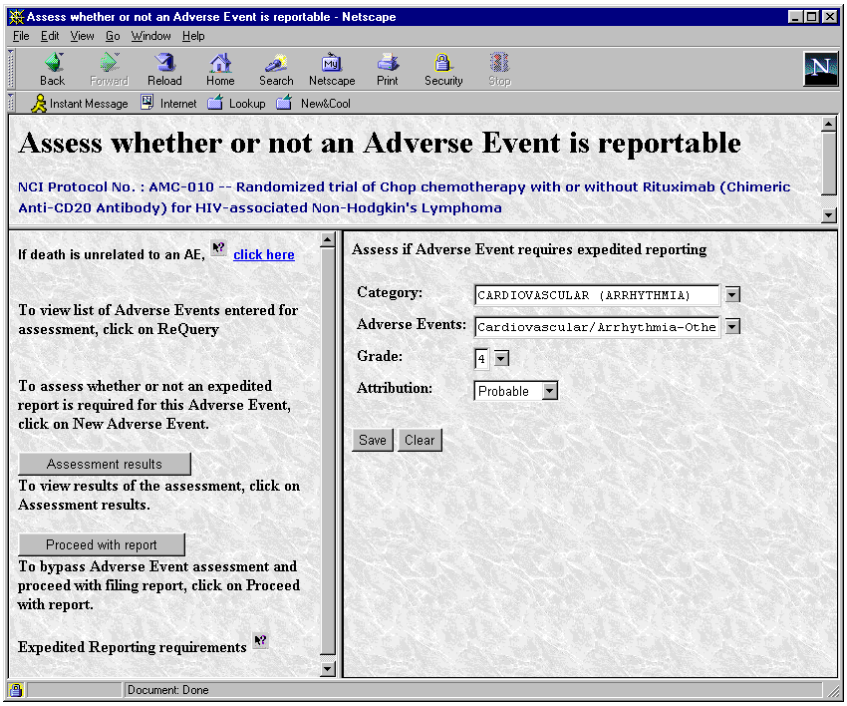

Figure 12 - Completed Check to Assess Whether or Not an Adverse Event is Reportable Screen

11. Click **Save**.

This saves the information currently displayed in the right frame.

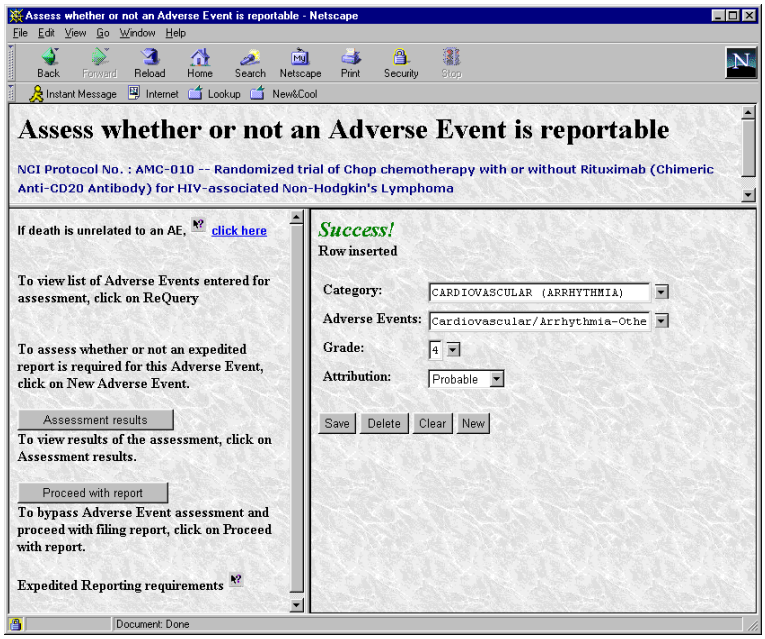

Figure 13 - Saved Checks to Assess Whether or Not an Adverse Event is Reportable Screen

12. Click **Assessment results** in the left frame.

    As shown in Figure 14, the assessment has been made that the event does require Expedited Reporting. Using CTEP criteria, as described on the following page, the AdEERS application determines the need for Expedited Reporting. **Regardless of the result of the assessment, the report can always be submitted**. The Assessment Section is simply a guide and its use is optional.

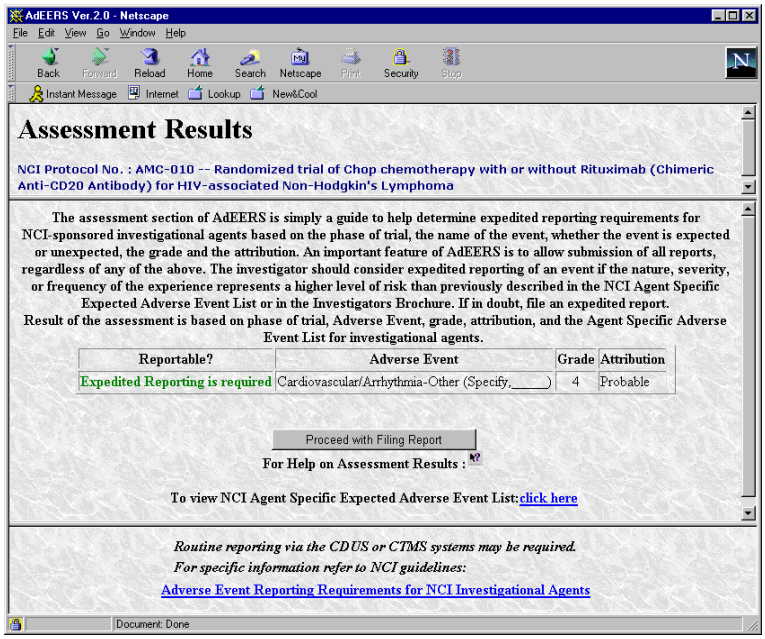

Figure 14 - Assessment Results Screen

The option **To view NCI Agent Specific Expected Adverse Event List:** may be selected to view a list of expected AE(s) by agent.

To review guidelines, click the link **Adverse Event Reporting Requirements for NCI Investigational Agents**.

The CTEP criteria for determining the need for Expedited Reporting follows:

Expedited Reporting is not required:

1. "Comments" do not exist for the event assessed whether the event is a CTC 2.0 term or "Other, Specify" selection.
2. The event assessed is an expected event and the grade and attribution do not fulfill the Expedited Reporting Requirements.
3. The event assessed is an unexpected event but the grade and attribution do not fulfill the Expedited Reporting Requirements.
4. "Other (Specify)" is assessed. "Comments" do not exist for the "Other (Specify)", and the grade and attribution do not fulfill the Expedited Reporting Requirements.

Expedited Reporting is required:

1. The event assessed is an expected event and the grade and attribution fulfill the Expedited Reporting Requirements.
2. The event assessed is an unexpected event and the grade and attribution fulfill the Expedited Reporting Requirements.
3. The event assessed is "Other (Specify)" with a grade and attribution that fulfill Expedited Reporting Requirements.
4. "Other (Specify)" is assessed. "Comments do not exist for the "Other (Specify)", and the grade and attribution fulfill the Expedited Reporting Requirements.

Adverse Event is NOT assessable:

1. This indicates that the AdEERS system cannot determine the reporting requirements of the event. The user, therefore, can view the Agent Specific Expected Adverse Event list to determine whether or not the event requires Expedited Reporting. "Other (Specify)" and/or "Comments" exist for the event assessed whether the event is a CTC 2.0 term or "Other, Specify" selection.

Enter Data for an Expedited Report for a New Patient

This procedure is used when no previous AdEERS report exists for a patient on this protocol, and therefore no pending or submitted report is associated with this Patient ID Number. This procedure assumes that Section Assess Whether or Not an Adverse Event Requires an Expedited Report in this document has been completed and begins with the screen in Figure 14.

1. Click **Proceed with Filing Report** on the **Assessment Results** Screen.

   The **Expedited Reports** screen appears, as shown in Figure 15. The following options are available on this screen:

   New Expedited Report - Select to create a new Expedited Report for a new patient.

   Copy a Report - Select to copy specific patient information from a submitted report to create a new Expedited Report.

   Amend a Report - Select to amend a previously submitted report.

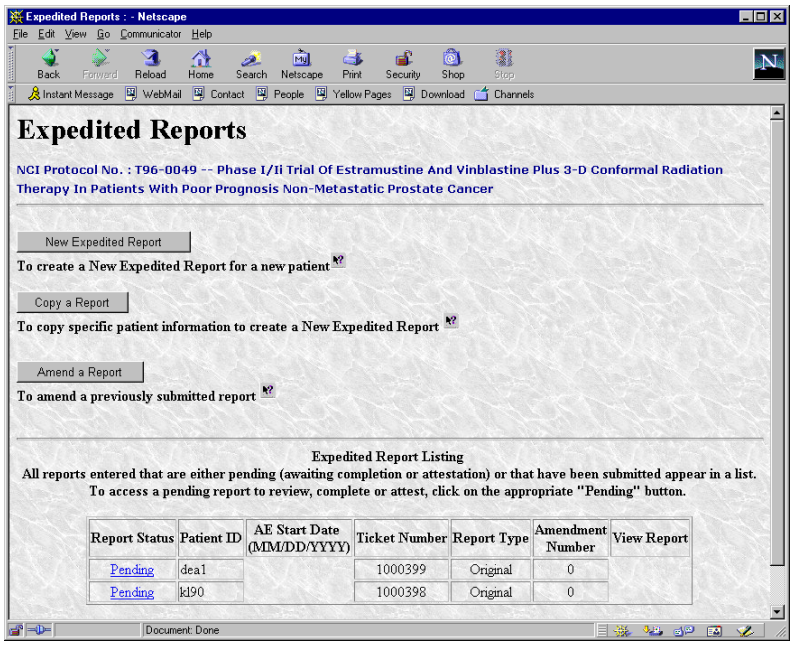

Figure 15 - Expedited Reports Screen

Enter Reporter Information

The **Reporter Information** screen allows for the entry of information about the Attending Physician if questions concerning the AE and patient would be more appropriately addressed by a clinician other than the investigator associated with the protocol.

1. Click **New Expedited Report**.

   The **Reporter Information** screen appears, as shown in Figure 16. The Reporter Information is pre-populated on the report based upon the username and password. PI Information appears on the printed report but will not appear on the screen.

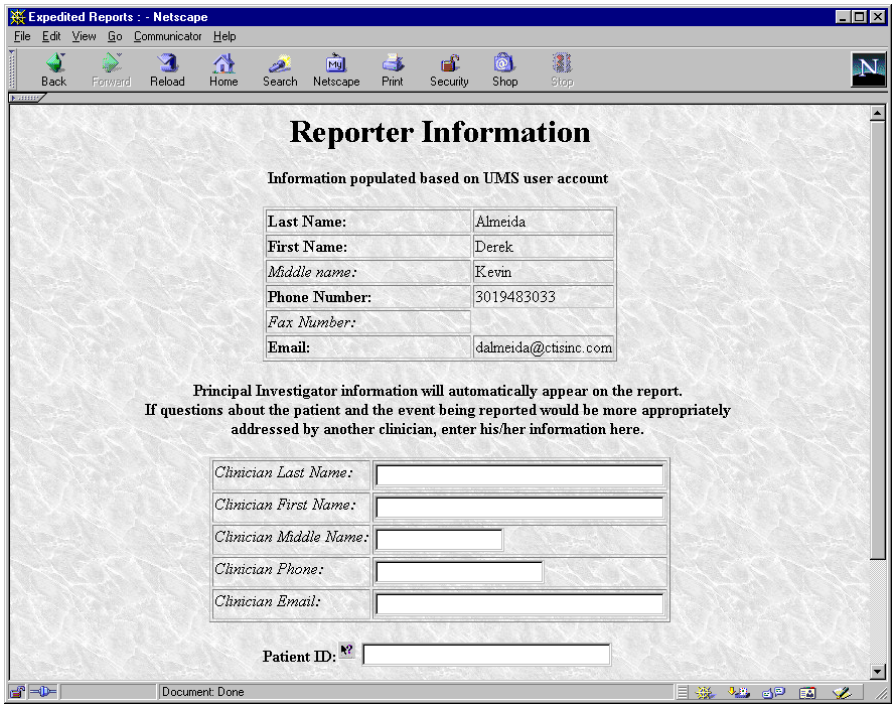

Figure 16 - Reporter Information Screen

2. Complete the following fields if the questions about the patient and event being reported would be more appropriately addressed by another clinician:

   Clinician Last Name:

   Clinician First Name:

   Clinician Middle Name:

   Clinician Phone:

   Clinician Email:

3. Enter the patient ID in the **Patient ID:** field.

   If the Patient ID Number entered matches the Patient ID Number of a patient previously reported in the NCI Clinical Data Update System (CDUS), some patient information data fields on the **Patient Information** screen will pre-populate.

4. Click **Save**.

   The information entered on the screen is saved. The **Sections of Report** screen appears, as shown in Figure 17.

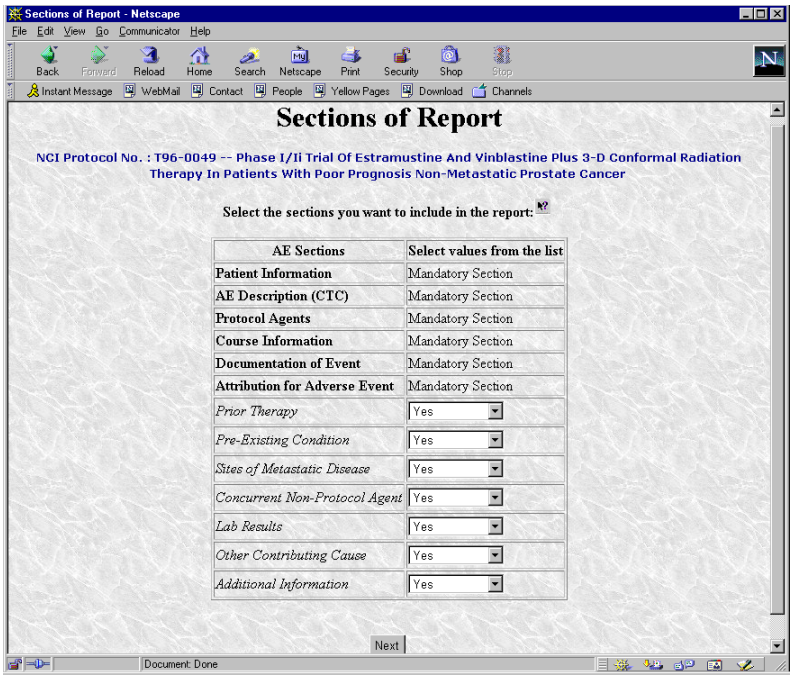

Figure 17 - Sections of Report Screen

Select Sections of Report

The sections chosen as inappropriate or not available for a patient will not appear in the left frame menu as the report data are entered. Only mandatory sections, and sections identified here as appropriate/available for a patient appear on subsequent screens.

1. Click the applicable down arrow to select **No** or **Not Available** for any **Report Sections** that are not applicable for this report.
2. Click **Next**.

   The AdEERS Menu appears, as shown in Figure 18. The menu displays mandatory sections and the sections selected on the previous screen as appropriate for this patient. The menu items listed are used to create a new report, modify a pending report, or submit a report. The menu items may be chosen in any order. Information entered in some sections is carried over to subsequent sections. Therefore, optimal completion of the report is accomplished by completing the sections in order. This User's Guide follows the top to bottom structure of the menu.

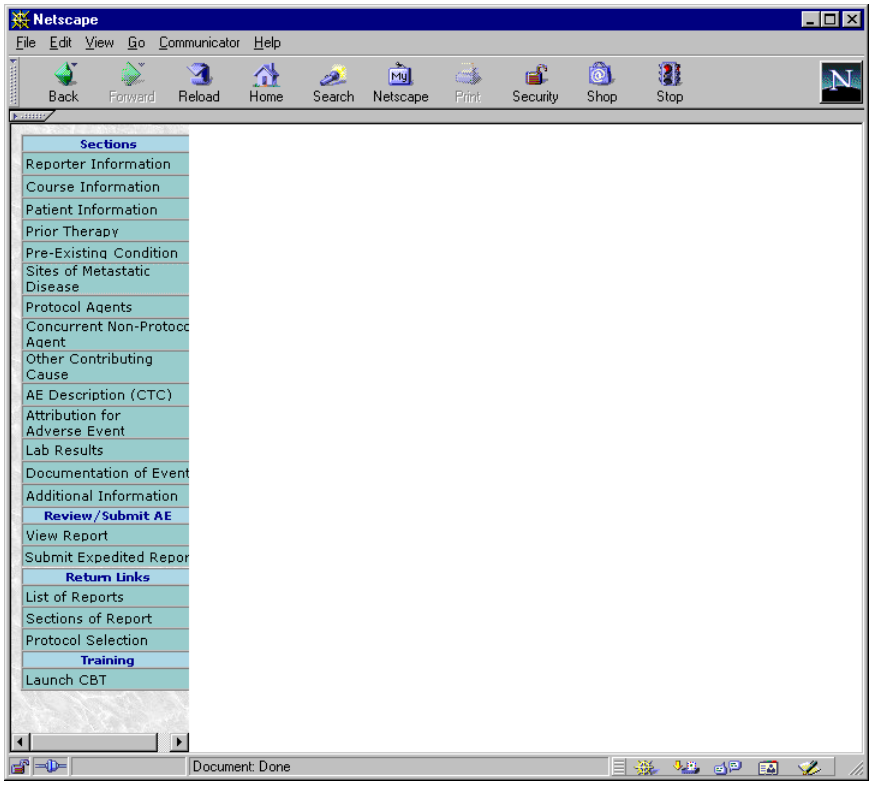

Figure 18 - AdEERS Menu

Review Reporter Information

This section will have been completed and need not be reaccessed. It can, however, be reviewed to verify Reporter Information. The Reporter Information is populated based on username and password. This information cannot be modified. Other Clinician information can be modified.

1. Click **Reporter Information** on AdEERS menu.

   The **Reporter Information** screen appears, as shown in Figure 19.

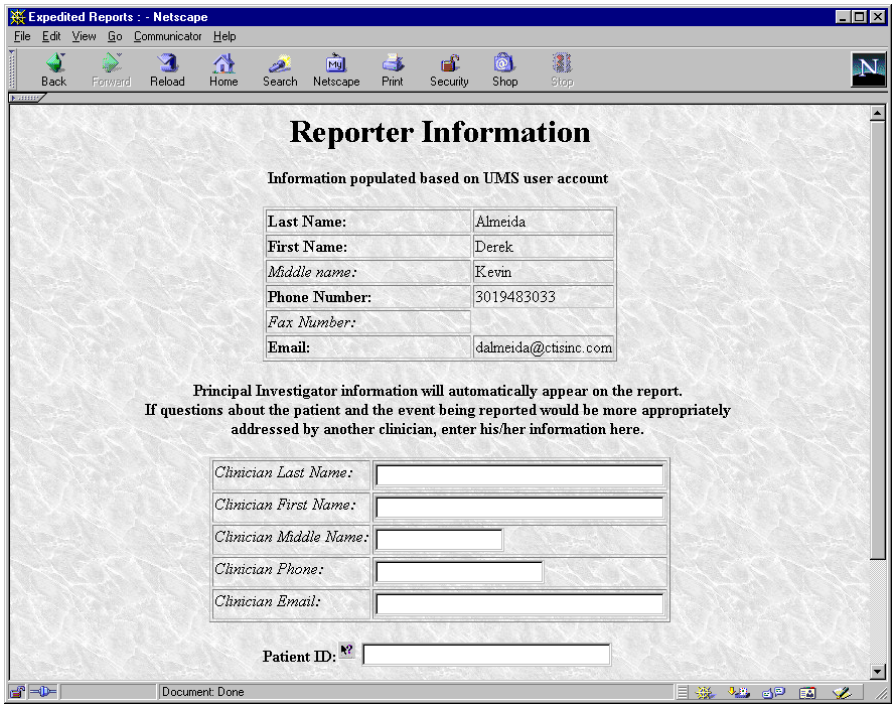

Figure 19 - Reporter Information Screen

2. Click **Save**.

   "Success" appears.

Enter Course Information

This screen is used to collect information about the course or cycle on which the event occurred.

A Treatment Assignment Code (TAC) is a short description (less than ten characters) of a treatment arm or dose level. If a TAC is not available in the LOV, information describing the treatment arm or dose level must be provided in the text box.

The Other Treatment Assignment Code is a treatment arm and/or dose level information that will appear on the Protocol Agent screen, and is a mandatory component of the final report.

TACs are supplied by CTEP and reviewed and approved by the study PI during the protocol approval process. TACs may or may not be available for older studies (Refer to Step 5 in the following procedure).

1. Click **Course Information** on AdEERS Menu.

   The **Course Information** screen, as shown in Figure 20, is displayed.

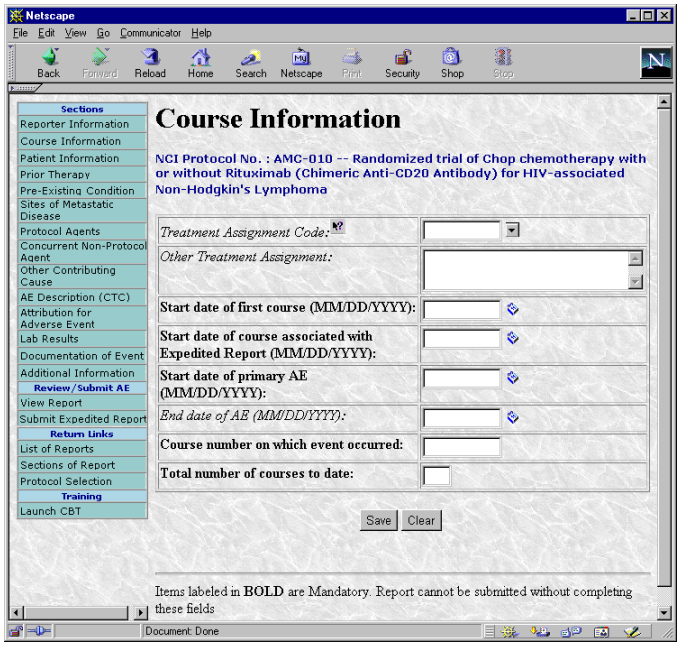

Figure 20 - Course Information Screen

2. Click the down arrow in the *Treatment Assignment Code:* field.

   The **List of Values: Treatment Assignment Code** appears.

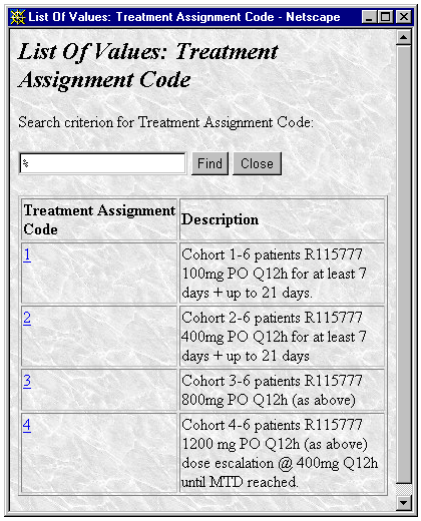

Figure 21 - List of Values: Treatment Assignment Code

3. Select the appropriate TAC.

   The TAC appears in the *Treatment Assignment Code:* field.

   The list is removed from the screen and the **Course Information** screen remains displayed.

4. If treatment assignment codes are not available from the list, enter the following information in the *Other Treatment Assignment:* field.

   - Each Agent name,
   - Dose,

- Route, and
- Administration schedule.

Either the ***Treatment Assignment Code*** field **or** *Other Treatment Assignment* field must be completed. Information about the treatment arm or dose level appears on the Protocol Agents screen later in the report.

5. Complete the following fields:

   Start date of first course (MM/DD/YYYY):

   Start date of course with Expedited Report (MM/DD/YYYY): The date on which the event occurred.

   Start date of primary AE (MM/DD/YYYY):

   End Date of AE (MM/DD/YYYY):

   Course number on which event occurred:

   Total number of courses to date:

6. Click **Save**.

   "Success" appears.

Enter Patient Information

This screen is used to collect information about the patient. If the Patient ID Number previously entered on the **Reporter Information** screen matches the Patient ID Number of a patient previously reported in the NCI Clinical Data Update System (CDUS), some patient information data fields will pre-populate. If the Patient ID Number entered is unique and unrecognized by CDUS, patient information data fields will not pre-populate. Consequently, all fields must be completed.

1. Click **Patient Information** on AdEERS Menu.

   The **Patient Information** screen, as shown in Figure 22, is displayed.

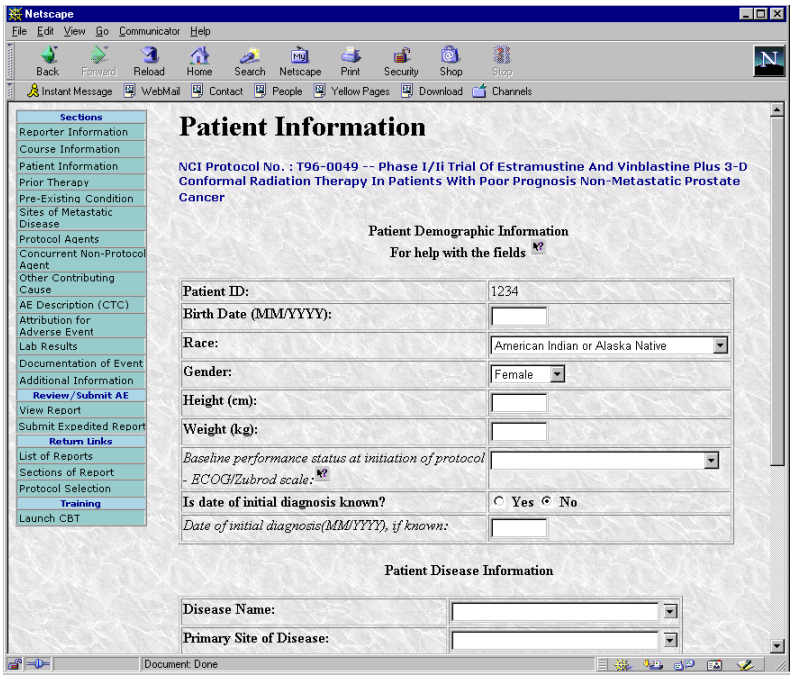

Figure 22 - Patient Information Screen

The **Patient ID:** field is pre-populated based on information entered on the **Reporter Information** screen. This field cannot be modified.

2. Enter the patient's birth date in the **Birth Date (MM/YYYY):** field. If the patient ID number matches the patient ID number of a patient previously reported in the NCI CDUS, the birth date will pre-populate. If the patient ID number entered is unique, the user must complete the birth date and all subsequent data fields.

3. Click the down arrow in the **Race:** field and select the patient's race from the available options. This field defaults to the first value on the list. The list must be viewed to supply the appropriate data.

4. Click the down arrow in the **Gender:** field and select the patient's gender from the available options. This field defaults to the first value on the list. The list must be viewed to supply the appropriate data.

5. Enter the patient's height in centimeters in the **Height (cm):** field.

6. Enter the patient's weight in kilograms in the **Weight (kg):** field.

7. Click the down arrow in the *Baseline performance status at initiation of protocol-ECOG/Zubrod scale:* field and select a value from the available options.

   Available options for this field are:
   0=Normal Activity, asymptomatic;
   1=Symptomatic, fully ambulatory;
   2=Symptomatic, in bed <50% of time;
   3=Symptomatic, in bed >50% of time; and
   4=100% bedridden.

8. Click **Yes** or **No** in the **Is date of initial diagnosis known?** field. If **Yes** is selected, the *Date of Initial Diagnosis* becomes mandatory. The default is **No**.

9. Enter the date of initial diagnosis in the *Date of Initial Diagnosis (MM/YYYY), if known:* field.

   Scroll down to view the remainder of this screen.

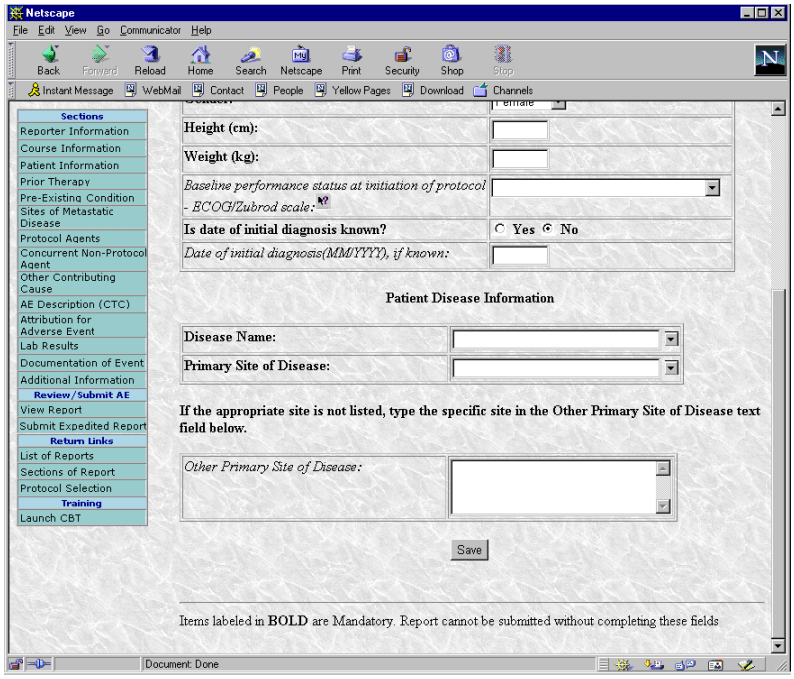

Figure 23 - Patient Information Screen

10. Click the **Disease Name:** field down arrow.

    The **List Of Values: Disease Name** appears, as shown in Figure 24. The LOV for diseases displays MedDRA terms. Many disease names include **NOS** (not otherwise specified) that provides a reportable general term for a wide range of related diseases. This list is best approached by first identifying the CATEGORY of disease followed by review of the diseases within each CATEGORY. AdEERS does not require specific details regarding disease name.

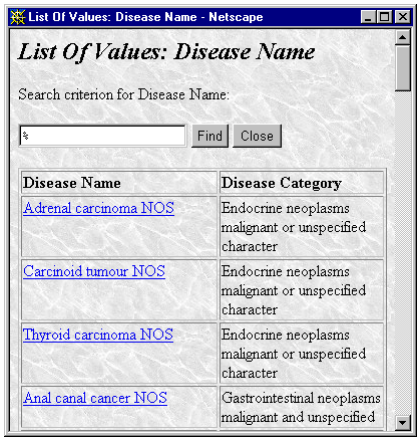

Figure 24 - List Of Values: Disease Name

11. Select the **Disease Name.**

    The Disease Name appears in the **Disease Name:** field.

12. Click the **Primary Site of Disease:** field down arrow.

    The List Of Values: Primary Site of Disease appears. The LOV is not restricted to the disease selected.

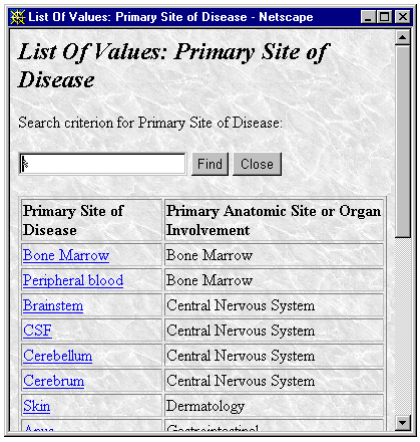

Figure 25 - List of Values: Primary Site of Disease

13. Select the **Primary Site of Disease**.

    The Disease Name appears in the **Primary Site of Disease:** field.

14. If the appropriate site is not available in the LOV, enter it in the *Other Primary Site of Disease:* field.

    The primary site of disease must be entered. Either the **Primary Site of Disease:** field or the *Other Primary Site of Disease:* field must be completed. The screen cannot be saved if data are entered in both fields.

15. Click **Save**.

    "Success" appears.

Enter Prior Therapies

This option is used to identify any prior therapy the patient had received. This information must be reported when it is available for the patient. All data fields must be entered and saved for one prior therapy at a time.

1. Click **Prior Therapies** on AdEERS Menu.

   The **Prior Therapy** screen appears. A MedDRA list of prior therapies will be displayed in the left frame. In the above example, no prior therapies exist for the patient. Since this is a new Expedited Report, the right frame is blank. **New** must be selected to enter information.

2. Click **New**.

   The right frame displays fields to enter new prior therapies, as shown in Figure 26.

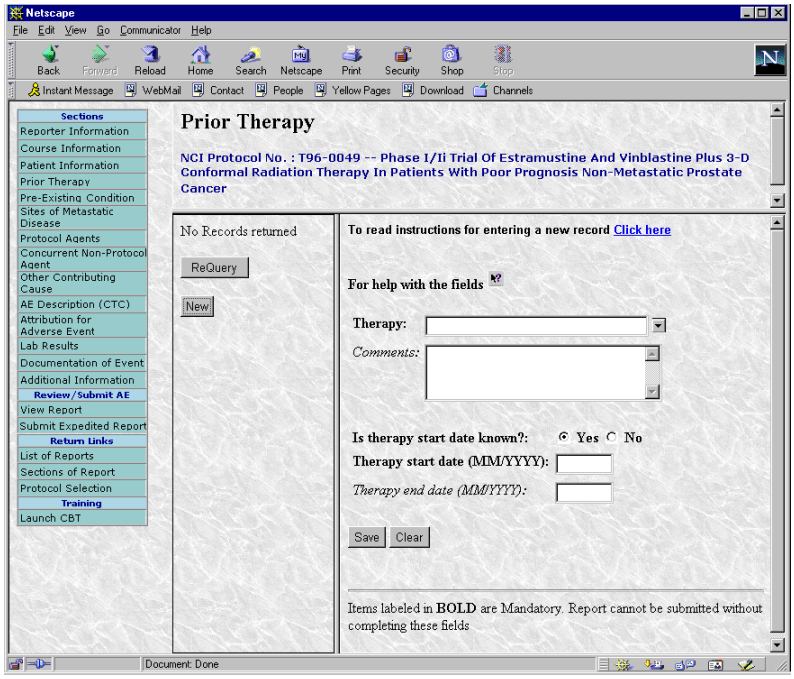

Figure 26 - Prior Therapy Screen

3. Click the down arrow in the **Therapy:** field.

   The **List of Values: Therapy** appears, as shown in Figure 27. Prior therapy information must be reported when it is available for the patient.

Figure 27 - List of Values: Therapy

4. Select the **Therapy**.

   The selected item appears in the **Therapy:** field.

5. Complete the following fields:

   Comments: Comments may be entered here.

Is therapy start date known? **Yes** or **No** is selected. If **Yes** is selected, **Therapy start date (MM/YYYY)** must be entered. No may be selected to bypass the limitation of entering only one month/year per record.

Therapy start date (MM/YYYY):

Therapy end date (MM/YYYY):

6. Click **Save**.

   "Success" appears.

   A subset of prior therapy selections requires further description using an associated LOV in the **Prior Therapy Agent(s):** section. If any of the following selections are chosen from the above LOV, the **Prior Therapy Agent(s)** field appears and must be completed.

   - Bone Marrow Transplant,
   - Chemotherapy NOS,
   - Chemotherapy Multiple Agents Systemic,
   - Chemotherapy Single Agent Systemic,
   - Hormonal Therapy, and
   - Immunotherapy.

   The list contains both the generic name and the brand name for agents frequently used in the treatment of cancer.

   The following steps assume that one of the selections listed above was selected:

7. Click **New** in either frame.

   The **Prior Therapy Agent(s)**screen appears, as shown in Figure 28.

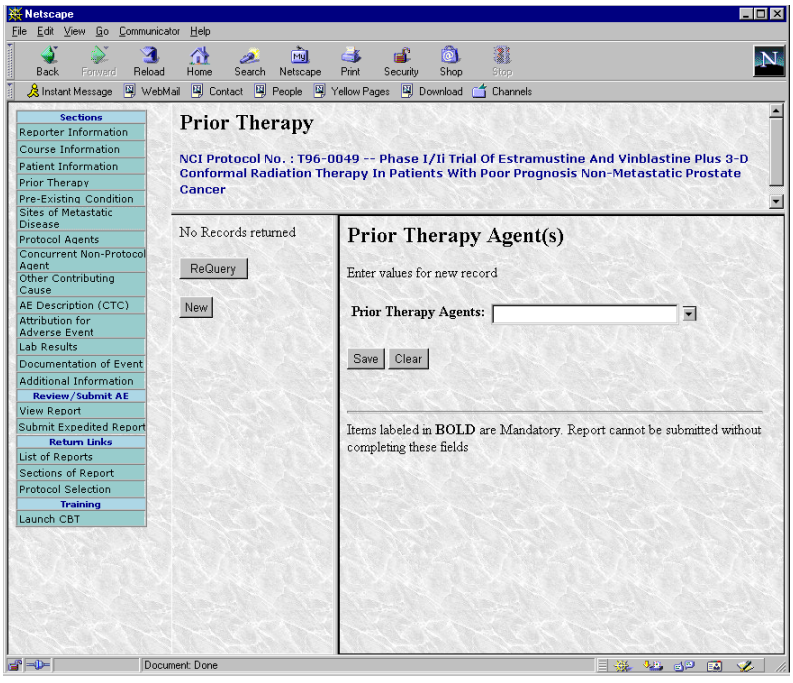

Figure 28 - Prior Therapy Agent(s) Screen

8. Click the down arrow in the **Prior Therapy Agents:** field.

   The **List of Values: Prior Therapy Agent(s)** appears, as shown in Figure 29.

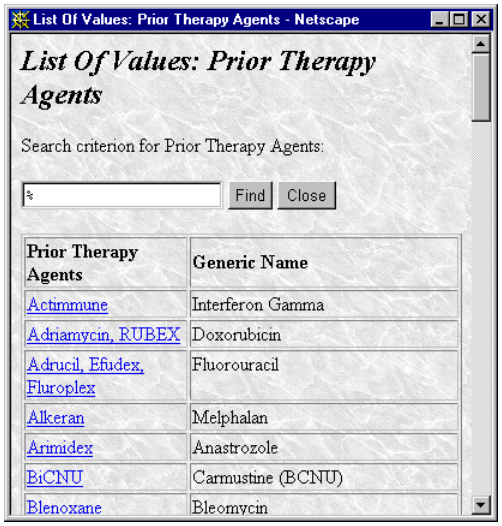

Figure 29 - List of Values: Prior Therapy Agents

9. Select the **Prior Therapy Agent**.

   The selected item appears in the **Prior Therapy Agents:** field.

10. Click **Save**.

    "Success" appears.

11. Click **ReQuery** in the left frame.

    This step is provided to show the effect of a ReQuery. The left frame is updated to show the newly entered prior therapy.

Figure 30 - ReQuery Results

Enter Pre-Existing Condition

The **Pre-Existing Condition** screen is used to identify any pre-existing condition(s) the patient had prior to the current protocol therapy. All data fields must be entered and saved for one pre-existing condition at a time.

1. Click **Pre-Existing Condition** on AdEERS Menu.

   The **Pre-Existing Condition** screen appears. Since this is a new Expedited Report, the right frame is blank. **New** must be selected to enter information.

2. Click **New**.

   The **Pre-Existing Condition** screen appears, as shown in Figure 31.

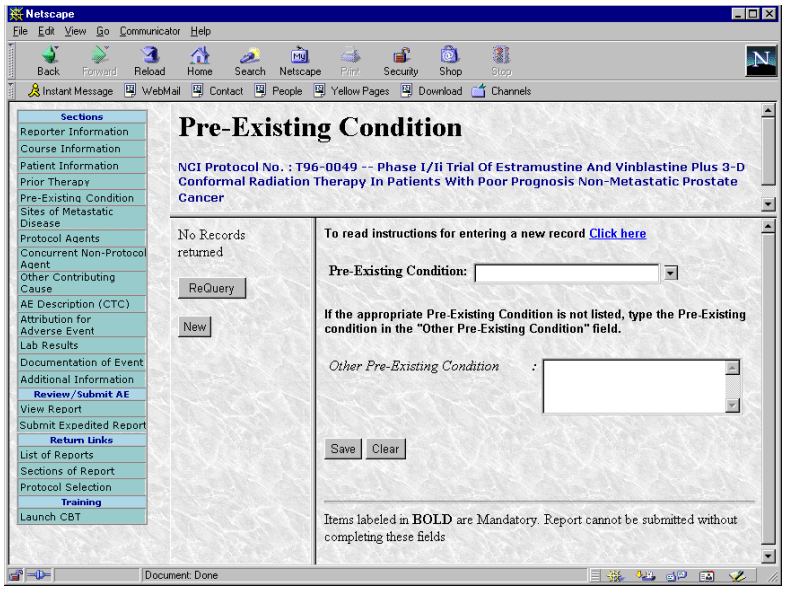

Figure 31 - Pre-Existing Condition Screen

3. Click the down arrow in the **Pre-Existing Condition:** field.

   The **List of Values: Pre-Existing Condition** appears. This list contains MedDRA terms.

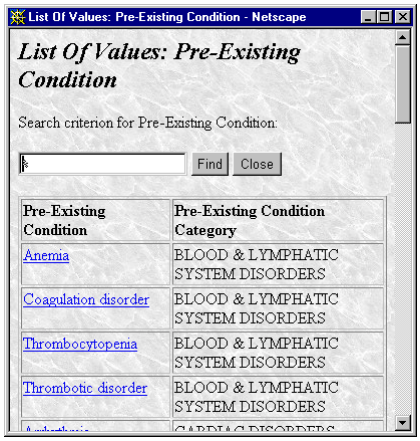

Figure 32 - List of Values: Pre-Existing Condition

4. Select the Pre-Existing Condition.

The selected item appears in the **Pre-Existing Condition:** field.

The next step is ONLY completed if the pre-existing condition was not available in the **List of Values**.

5. Enter any other pre-existing condition in the *Other Pre-Existing Condition:* field.
6. Click **Save**.

   "Success" appears.

Enter Site(s) of Metastatic Disease

The **Sites of Metastatic Disease** screen is used to identify the physical location of the patient's disease. All data fields must be entered and saved for one metastatic disease at a time.

1. Click **Sites of Metastatic Disease** on AdEERS Menu.

   The **Site of Metastatic Disease** screen appears. Since this is a new Expedited Report, the right frame is blank. **New** must be selected to enter information.

2. Click **New**.

   Site of Metastatic Disease fields appear in the right frame.

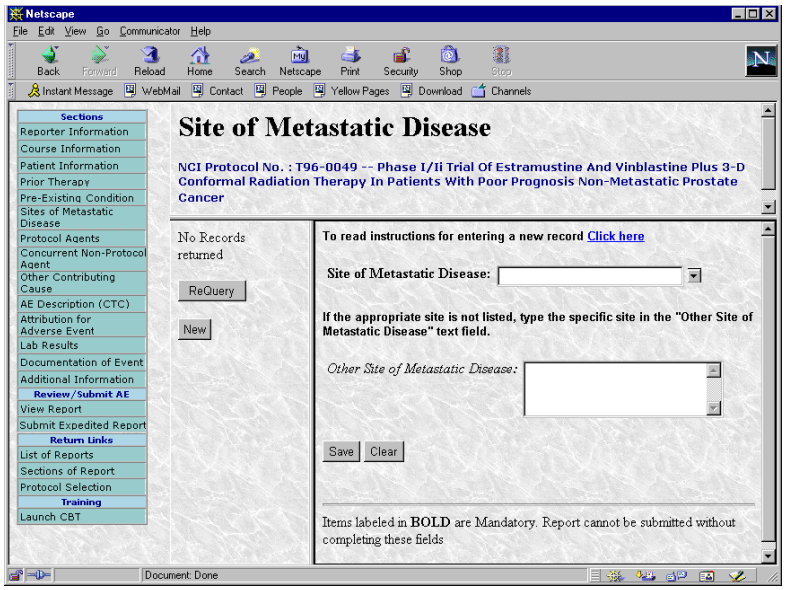

Figure 33 - Site of Metastatic Disease Screen

3. Click the down arrow in the **Site of Metastatic Disease:** field.

   The **List of Values: Site of Metastatic Disease** appears, as shown in Figure 34.

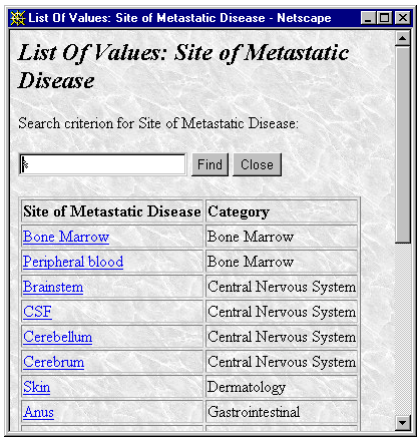

Figure 34 - List of Values: Site of Metastatic Disease

4. Select the Site of Metastatic Disease.

   The selected item appears in the **Site of Metastatic Disease:** field.

   The next step is ONLY completed if the site of metastatic disease was not available in the **List of Values**.

5. Enter any other body site in the *Other Site of Metastatic Disease:* field.

6. Click **Save**.

   "Success" appears.

Enter Protocol Agent

This screen is used to collect information about the protocol agent. All data fields must be entered and saved for one agent at a time.

1. Click **Protocol Agents** on AdEERS Menu.

   The **Protocol Agent** screen appears, as shown in Figure 35. Since this is a new Expedited Report, the right frame is blank. **New** must be selected to enter information.

2. Click **New**.

   Protocol agent fields appear in the right frame.

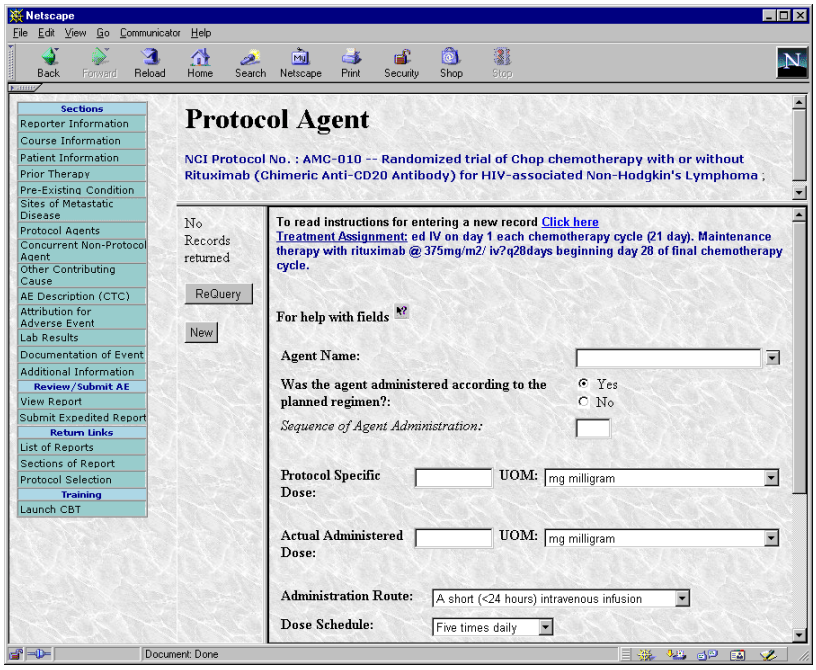

Figure 35 - Protocol Agent Screen

The TAC was identified in the Course Information section. The dose level or treatment arm information appropriate for the TAC chosen appears. If the protocol selected did not have a TAC available from the LOV, information describing the dose level or treatment arm (agent name, dose, route, and schedule) that was entered on the **Course Information** screen appears.

3. Click the down arrow in the **Agent Name:** field.

   The **List of Values: Agent Name** appears. This includes all agents in all TACs (arms and dose levels) for the protocol selected. All agents appropriate for the TAC must be selected. However, one agent must be selected at a time and all data fields completed and saved. Subsequent agents are to be selected and completed one at a time.

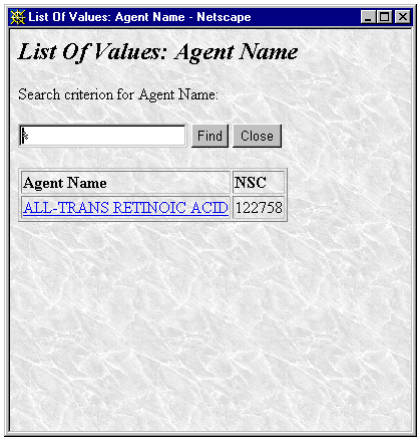

Figure 36 - List of Values: Agent Name

4. Select the **Agent Name**.

   The selected item appears in the **Agent Name:** field.

5. Complete the following fields:

   Was the agent administered according to the planned regimen?: Yes is the default for this field. If **No** is selected, when the screen is saved, the **Agent Adjustment** screen, shown in Figure 37, is displayed.

   Sequence of Agent Administration: (e.g., first =enter 1, second =enter 2, etc.) This field should be completed only for those agents listed on the protocol (not concurrent drugs).

   Protocol Specific Dose: The total amount of agent calculated for this patient as specified by the TAC (treatment or dose level) of the protocol for one dose (i.e. planned dose).

   UOM: Select the unit of measure from the pull down list (i.e. mg, Gm).

   Actual Administered Dose: Amount given for the course (cycle)

   UOM: Select the unit of measure from the pull down list.

   Administration Route: Select from the pull down list.

   Dose Schedule: Select from the pull down list.

   Complete the following step only if the dose schedules available in the **Dose Schedule** pull down list did not provide a correct schedule.

   Administration Schedule: Enter the schedule (e.g., days 1 - 5, days 1,3,5, etc).

6. Click **Save**.

   "Success" appears.

Note: If the question **Was the agent administered according to the planned regimen?:** was answered **No**, the Agent Adjustment screen appears, as shown in Figure 37.

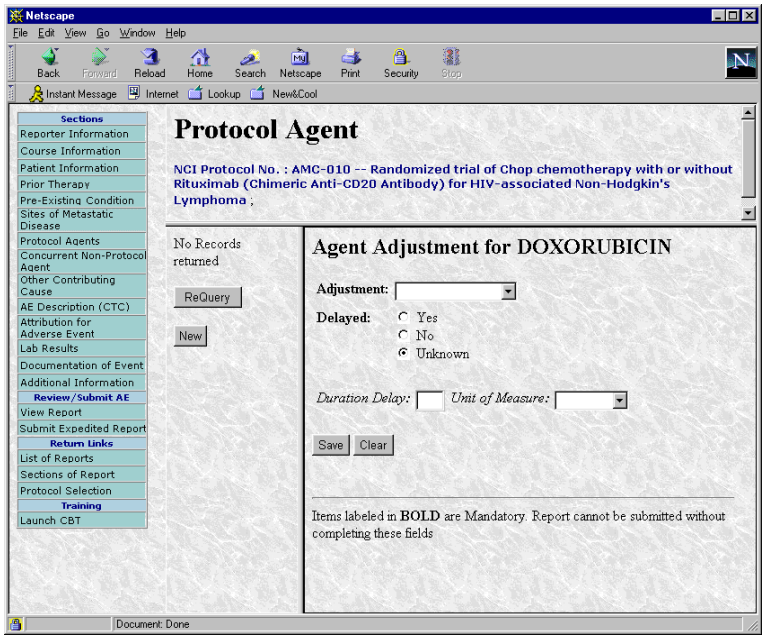

Figure 37 - Agent Adjustment Screen

7. Complete the following fields:

   Adjustment: Select from the pull down list.

   Delayed: **Yes**, **No**, or **Unknown** is selected. **Unknown** is the default.

   Duration Delay: Enter the duration delay, if any.

   Unit of Measure: Select from the pull down list, if applicable.

Enter Concurrent Non-Protocol Agent

This screen is used to record any non-protocol agent administered to the patient concurrently with protocol agent. Agents must be entered and saved one at a time.

1. Click **Concurrent Non-Protocol Agent** on AdEERS Menu.

   The **Concurrent Non-Protocol Agent** screen appears. Since this is a new Expedited Report, the right frame is blank. **New** must be selected to enter information.

2. Click **New**.

   Concurrent non-protocol agent fields appear in the right frame, as shown in Figure 38.

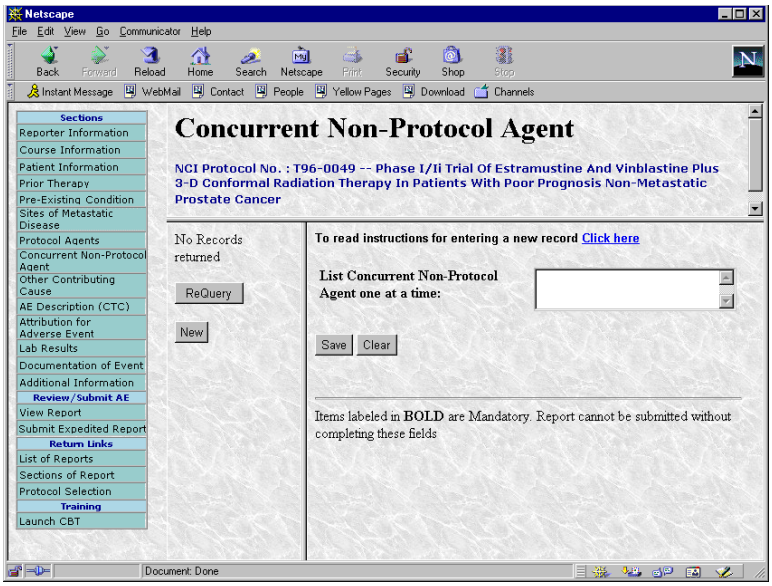

Figure 38 - Concurrent Non-Protocol Agent Screen

3. Type the name of the agent in the **List Concurrent Non-Protocol Agent one at a Time:** field.

4. Click **Save**.

   "Success" appears.

Enter Other Contributing Cause

This screen is used to describe factors, other than a protocol or non-protocol agent, which may have contributed to the Adverse Event. Other causes must be entered and saved one at a time.

1. Click **Other Contributing Cause** on AdEERS Menu.

The **Other Contributing Cause** screen appears. Since this is a new Expedited Report, the right frame is blank. **New** must be selected to enter information.

2. Click **New**.

   Other contributing cause fields appear in the right frame, as shown in Figure 39.

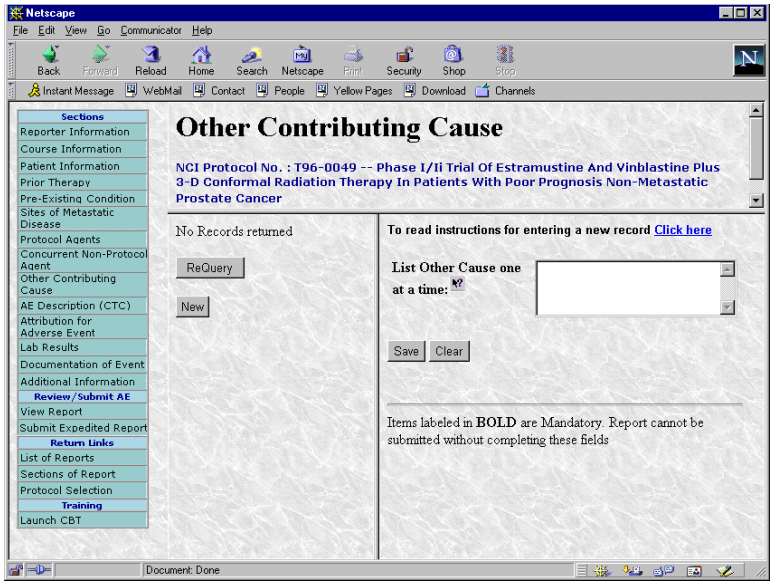

Figure 39 - Other Contributing Cause Screen

3. Type the name of the cause in the **List Other Cause one at a time:** field.

4. Click **Save**.

   "Success" appears.

Enter AE Description (CTC)

This screen is used to describe AE(s). As shown in this example, events entered earlier in the Assess Whether or Not an Adverse Event Requires an Expedited Report Section appear. AdEERS requires that AE(s) be reported using the terms and grades criteria listed in the NCI Common Toxicity Criteria, Version 2.0 (CTC v2.0).

This procedure uses the standard data entry method to enter AE descriptions. An alternative method is to use the CTC Interactive Web Application to enter descriptions. This option may be selected from the left frame. If the Web application method is used, options are available to Search by CATEGORY, Search by Toxicity, or Search by Index. The web application is the most comprehensive approach to identify the appropriate CTC term and grade.

1. Click **AE Description (CTC)** on AdEERS Menu.

   The **AE Description (CTC)** screen appears, as shown in Figure 40. AE(s) entered in the Assessment section appear on the report. These may be modified or deleted if necessary.

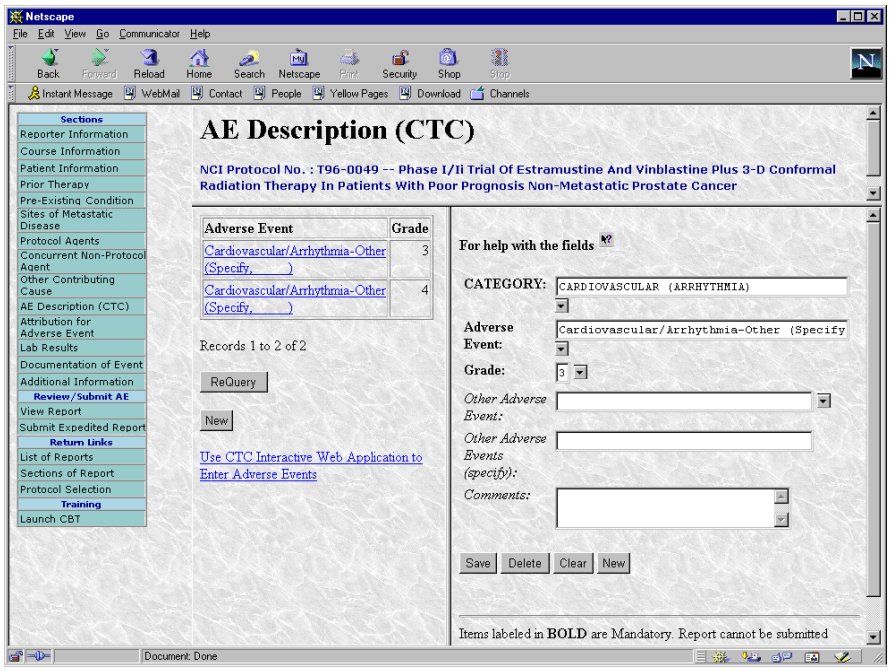

Figure 40 - AE Description (CTC) Screen

Complete the fields in *italics* only if **Other (Specify)** was chosen in the **Adverse Event:** field.

This field is used to used to collect new events for evaluation and, if approved, addition in future versions of the CTC.

If an appropriate term is not identified, the event is to be reported by identifying the CTC CATEGORY and selecting **Other (Specify)**. Specific information regarding this is to be reported in one of two ways:

View the LOV for Other Adverse Event: AdEERS contains a catalogue, the Agent Specific Adverse Event List, of expected (known) events for the agents included in each protocol.

If the **Other (Specify)** event being reported **is included** on the Agent Specific Adverse Event List, choose it from the LOV in the *Other Adverse Event:* field.

If the event being reported **is not included** on the Agent Specific Event List it will not appear in the LOV and must be entered in the *Other Adverse Events (specify):* field.

Selecting an **Other (Specify)** Adverse Event from any CTC CATEGORY automatically causes one of these two data fields to become mandatory: either *Other Adverse Event:* or *Other Adverse Events (specify):*.

2. Click the down arrow in the *Other Adverse Event:* field.

   The **List of Values: Other Adverse Event** appears, as shown in Figure 41.

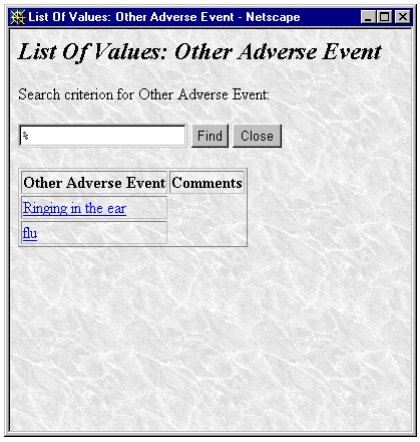

Figure 41 - List of Values: Other Adverse Event

3. Select the **Other Adverse Event**.

   The selected option appears in the *Other Adverse Event:* field.

4. Enter any other AE(s) in the *Other Adverse Events (specify):* field.

5. Enter any comments in the *Comments:* field.

6. Click **Save**.

   "Success" appears.

Enter Attribution for Adverse Event

This screen is used to assign attribution to the protocol agent, disease, concurrent non-protocol agent, and other contributing cause. Attribution is the relationship to agent/intervention.

All AE(s) entered in this report appear on this screen. Each AE is evaluated to determine what might have caused the event or what interventions or conditions the event might have been attributed to. Evaluation of AE(s) involves assessing the relationship of the event to all of the following:

- the investigational agent,
- the disease,
- concurrent non-protocol agents, and
- other causes.

Agent and disease information is mandatory in Expedited Reports. Therefore, agent and disease information must be entered, saved, and addressed in this section before a report can be submitted. Because concurrent non-protocol agents and other causes are not applicable for all patients, if information has not been entered for these two sections of the report, only the Protocol Agents and the Disease will appear on the table and require assignment of attribution.

1. Click **Attribution for Adverse Event** on AdEERS Menu.

   The **Attribution for Adverse Event** screen, as shown in Figure 42, is displayed. The fields displayed will vary depending upon the AE and the protocol agent(s), disease, concurrent non-protocol agent(s), and other contributing cause(s).

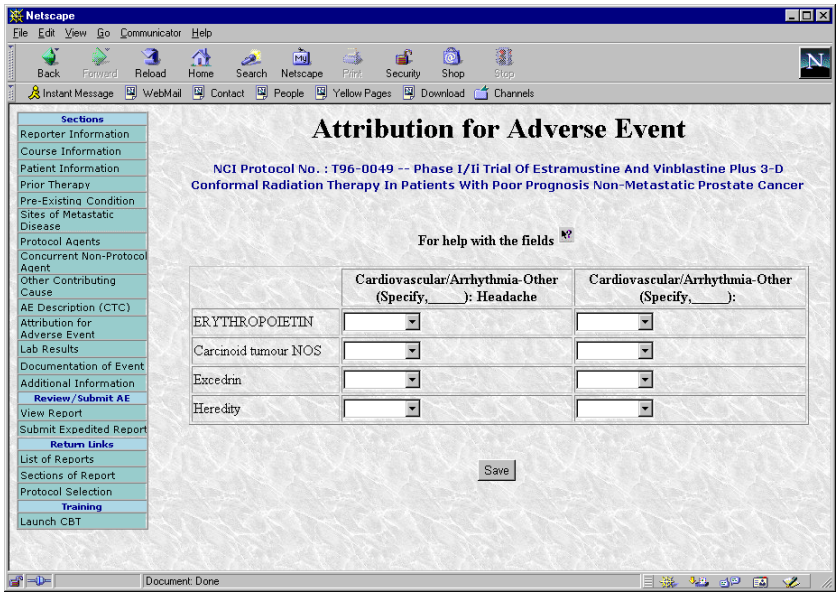

Figure 42 - Attribution for Adverse Event Screen

2. Click the down arrow in each field and select an attribution from the available options.
3. Click **Save**.

   "Success" appears.

For more information about Attribution of Adverse Events, refer to AdEERS CBT: http://ctep.info.nih.gov/AdEERS/default.htm.

Enter Lab Result

This screen is used to collect information concerning any lab results associated with the event being reported.

1. Click **Lab Result** on AdEERS Menu.

   The **Lab Result** screen appears, as shown in Figure 43. Since this is a new Expedited Report, the right frame is blank. **New** must be selected to enter information.

2. Click **New**.

Lab result fields appear in the right frame.

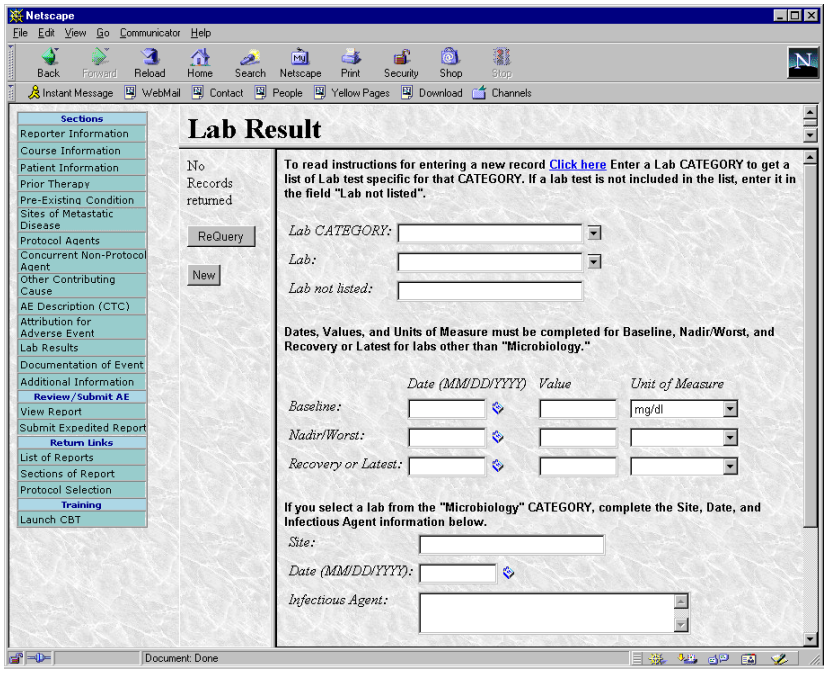

Figure 43 - Lab Result Screen

3. Click the *Lab CATEGORY:* field down arrow.

   The **List Of Values: Lab CATEGORY** appears. This list contains the lab categories.

Figure 44 - List Of Values: Lab CATEGORY

4. Select the **Category**.

   The selected item appears in the *Lab CATEGORY:* field.

5. Click the *Lab:* field down arrow.

   The **List Of Values: Labs** appears, as shown in Figure 45, for the Lab CATEGORY previously selected.

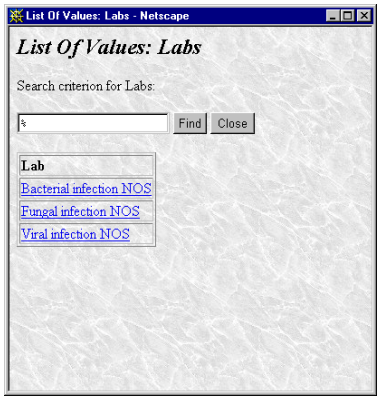

Figure 45 - List Of Values: Labs

6. Select the **Labs**.

   The selected item appears in the *Lab:* field.

7. Type the name of the lab in the *Lab not listed:* field **IF** the required *Lab* was not found in the **List of Values: Labs**.

8. Complete the following fields only if the desired *Lab CATEGORY* selected from the list was not **Microbiology**:

   Baseline:

   Date (MM/DD/YYYY)

   Value

   Unit of Measure

   Nadir/Worst:

   Date (MM/DD/YYYY)

   Value

   Unit of Measure

   Recovery or Latest:

   Date (MM/DD/YYYY)

   Value

   Unit of Measure

9. Complete the following fields only if **Microbiology** was selected for *Lab CATEGORY*:

   Microbiology:

   Date (MM/DD/YYYY):

   Infectious Agent:

10. Click **Save**.

    "Success" appears.

Enter Documentation of Event

This screen is used to provide a description of an event and temporal relationship to the investigational agent. Options are also provided to describe retreatment and outcome.

Note: If the death being reported is unrelated to the AE, an additional field**, Cause of Death**, appears on the **Documentation of Event** screen. The available options for this field are: Accident, Homicide, Progressive Disease, Sudden Death, Suicide, and Unknown.

1. Click **Documentation of Event** on AdEERS Menu.

   The **Documentation of Event** screen is displayed.

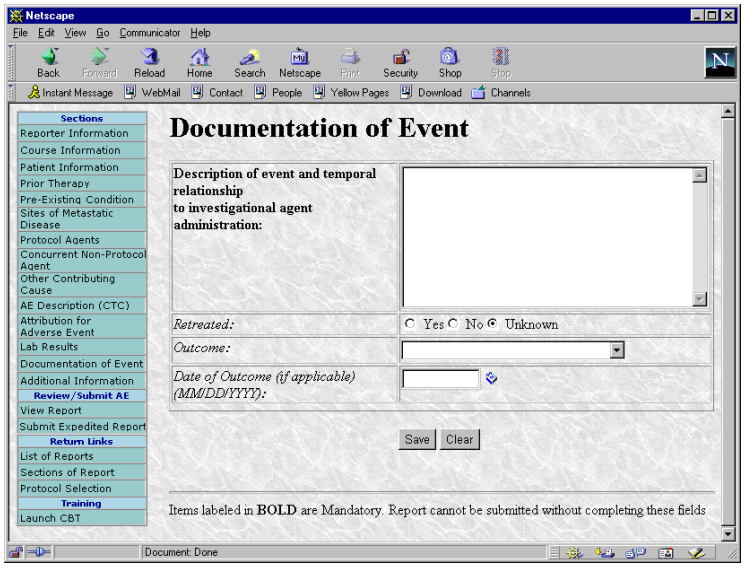

Figure 46 - Documentation of Event Screen

2. Type a description of the event and temporal relationship to the investigational agent in the **Description of event and temporal relationship to investigational agent administration:** field.
3. Select **Yes**, **No**, or **Unknown** in the *Retreated:* field.
4. Click the down arrow in the *Outcome:* field and select an outcome from the available options.
5. Enter the date of the outcome, if any, in the *Date of Outcome (if applicable) (MM/DD/YYYY):* field.
6. Click **Save**.

   "Success" appears.

Note: If the outcome for the patient was Fatal/Died, the Death/Autopsy Information screen appears, as shown in Figure 47, pre-populated from previously entered information.

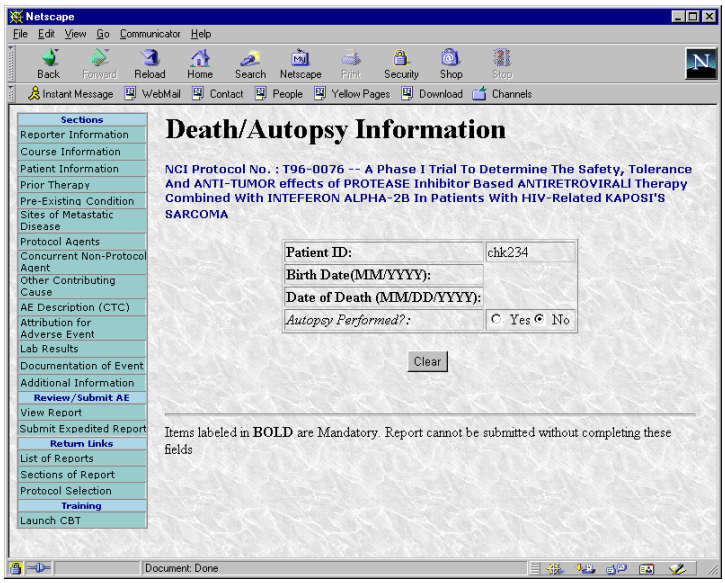

Figure 47 - Death/Autopsy Information Screen

7. Click **Yes** if an autopsy was performed.
8. Click **Save**.

   "Success" appears.

Enter Additional Information

This screen is used to identify separate documents that will be submitted with the Expedited Report. Adobe Acrobat Reader must be installed on your computer to view the report.

1. Click **Additional Information** on AdEERS Menu.

   The **Additional Information** screen appears, as shown in Figure 48.

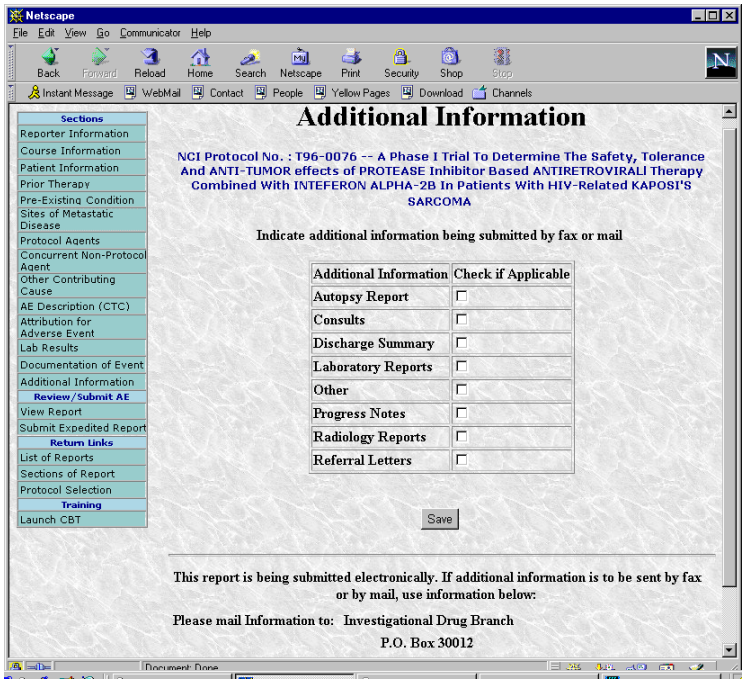

Figure 48 - Additional Information Screen

2. Click any additional items that will be submitted with the Expedited Report.
3. Click **Save**.

   "Success" appears.

Submit a Pending Report

A pending report may be submitted at any time once the required information is entered. Pending reports may be submitted to NCI by users with account privileges of attestation and submission. Attestation privileges always include submission privileges. The following steps document this process from the initial AdEERS screen. A report may also be submitted by selecting the **Submit Expedited Report** menu item on the AdEERS Main Menu.

1. Select **Submit an Expedited Report for an NCI Sponsored Investigational Agent**, as shown in Figure 49.

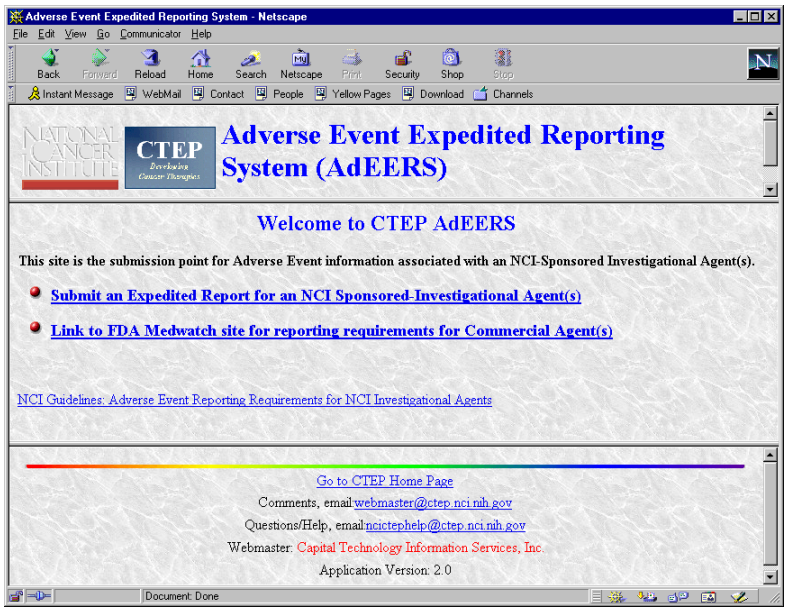

Figure 49 - AdEERS Main Menu - Adverse Event Expedited Reporting System (AdEERS)

A screen appears with a table of protocols available for selection. This table shows the NCI Protocol Numbers and the title of the protocol.

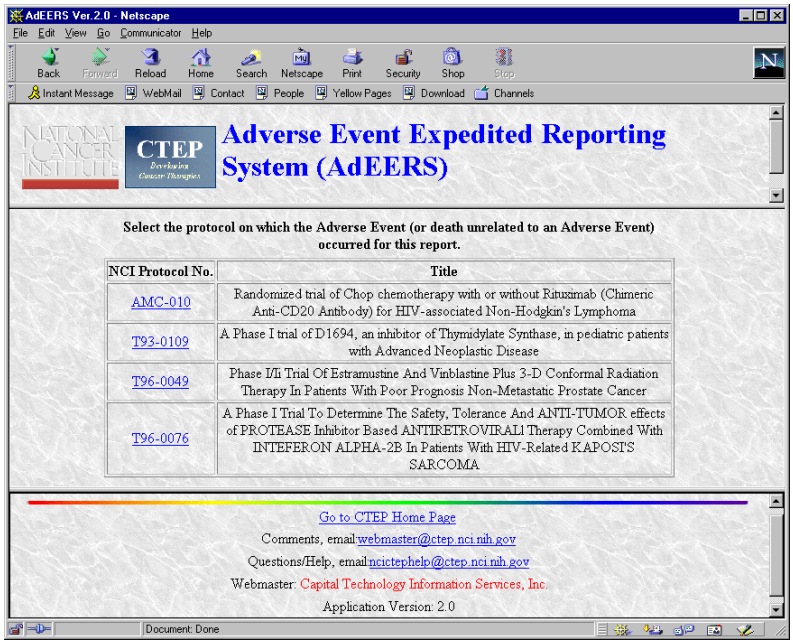

Figure 50 - NCI Protocols Available for Submission of Adverse Event Reports Screen

2. Click the NCI Protocol Number for which a report is to be submitted.

   The **Assess Whether or Not an Adverse Event(s) is Reportable** screen appears, as shown in Figure 51. The following options are available in the left frame of this screen:

   If death is unrelated to an AE, click here - Select to assess AE(s) where a death was unrelated to the AE.

   ReQuery - Select to view a list of AE(s) entered for assessment.

New Adverse Event - Select to begin the check to determine if an AE is reportable.

Assessment results - Select to view the results of a **New Adverse Event** check.

Proceed with report - Select to bypass the checks to determine if an AE is reportable.

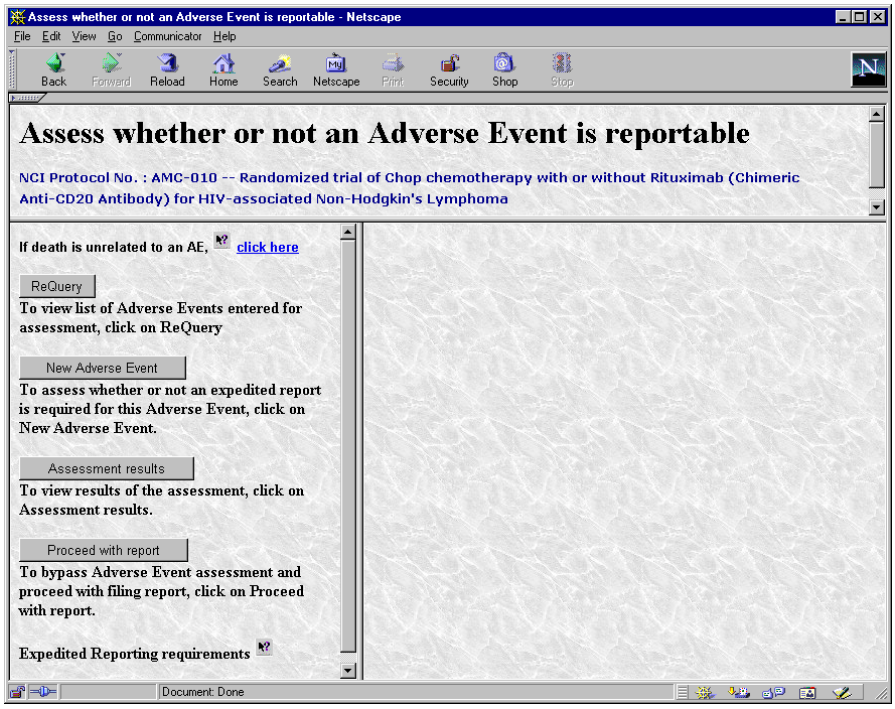

Figure 51 - Assess Whether or Not an Adverse Event is Reportable Screen

3. Click **Proceed with report** to continue with the submission of the report.

The **Expedited Reports** screen appears, as shown in Figure 52, with a listing of reports that are pending for the selected protocol.

Scrolling may be necessary to select the report to be submitted.

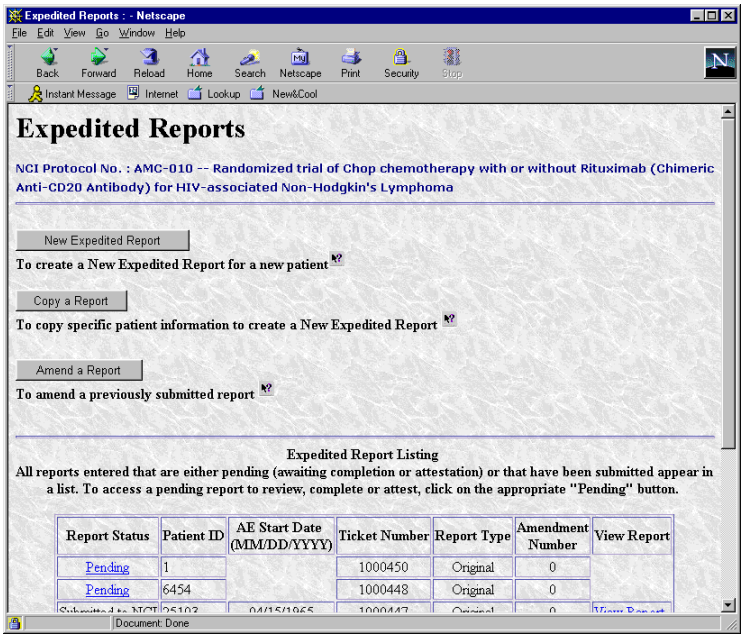

Figure 52 - Expedited Reports Screen

4. Click the **Pending** link under **Report Status** to select the report to be submitted.

   The **Sections of Report** screen appears, as shown in Figure 53.

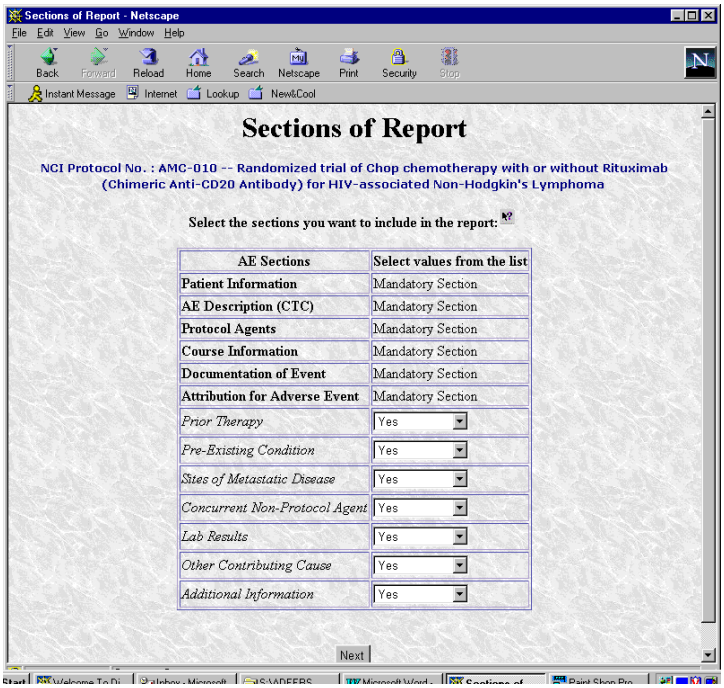

Figure 53 - Sections of Report Screen

5. Click the applicable down arrow to select **No** or **Not Available** for any **Report Sections** that are not applicable for this report.

6. Click **Next**.

   Depending upon the amount of information currently entered for the pending report, some sections may need to be completed. If information is missing from a section identified as appropriate for this report, the **AE Pending Sections** screen appears, as shown in Figure 54.

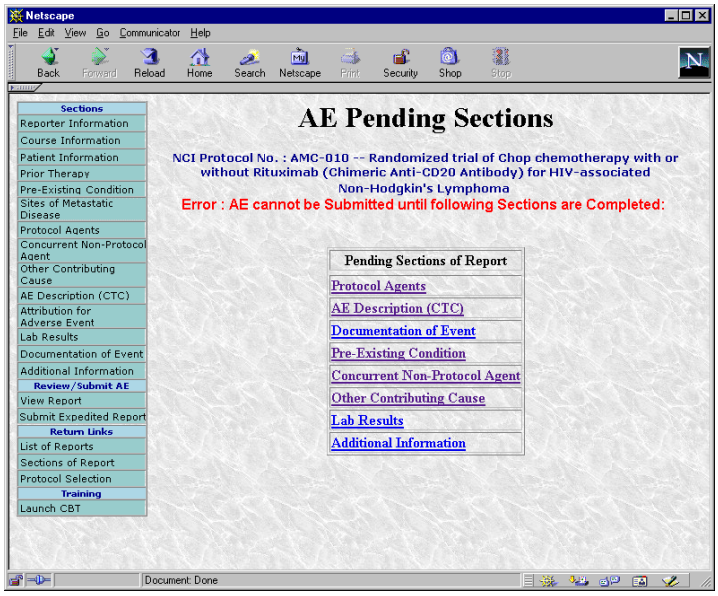

Figure 54 - AE Pending Sections Screen

To complete the report, click any section identified as incomplete and provide necessary information before submitting; or, click **Sections of Report** on the AdEERS menu to change the identified incomplete item in the list from **Yes** to **No** or **Not Available**.

Refer to sections Enter Reporter Information through Enter Additional Information on pages 17 through 43 to complete the necessary sections.

7. Click **Submit Expedited Report** on the AdEERS menu.

   The **Submit Expedited Report** screen appears, as shown in Figure 55.

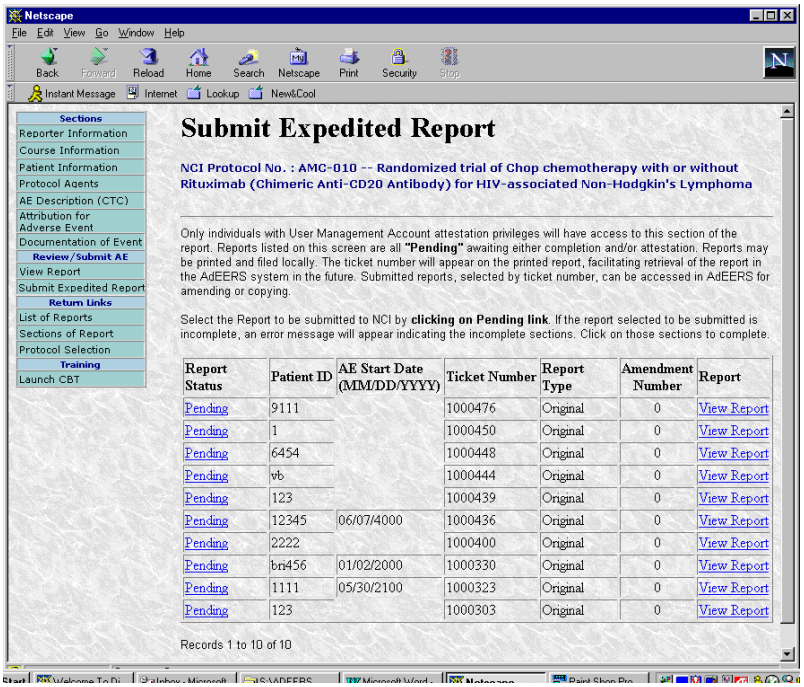

Figure 55 - Submit Expedited Report Screen

8. Click the **Pending** link of the report to be submitted.

   The **Attester Information** screen appears, as shown in Figure 56. Attester information displayed is based on user account information.

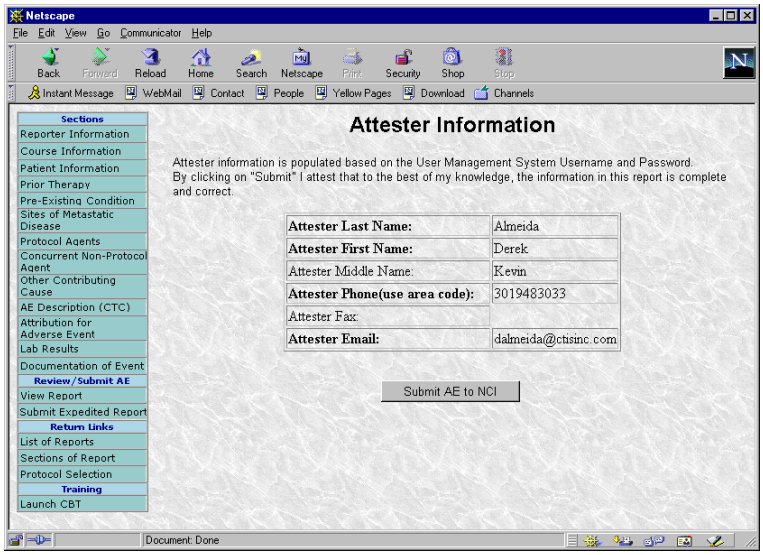

Figure 56 - Attester Information Screen

9. Click **Submit AE to NCI** to submit the report to NCI.

   A message indicating success appears at the top of the screen.

Copy an Expedited Report

Some patient information in submitted reports can be reused to create a new report. The purpose of the **Copy** feature is to facilitate creation of multiple reports for the same patient, reusing patient information from the following sections:

- Patient Information,
- Pre-Existing Condition,
- Prior Therapy, and
- Sites of Metastatic Disease.

The **Copy** option is available only from the **Expedited Report** screen. This example documents the procedure to copy an Expedited Report that is pending.

1. Select **Submit an Expedited Report for an NCI Sponsored Investigational Agent**, as shown in Figure 57.

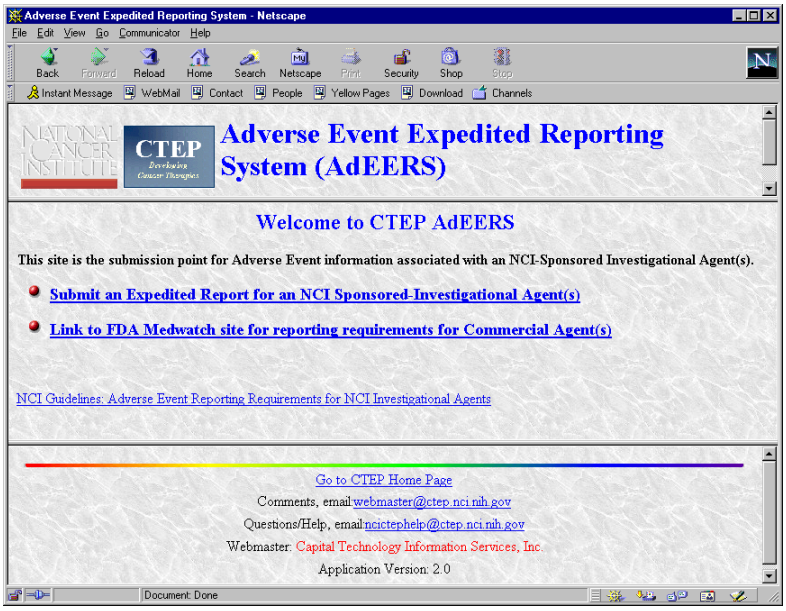

Figure 57 - AdEERS Main Menu - Adverse Event Expedited Reporting System (AdEERS)

A screen appears with a table of protocols available for selection. This table shows the NCI Protocol Numbers and the title of the protocols.

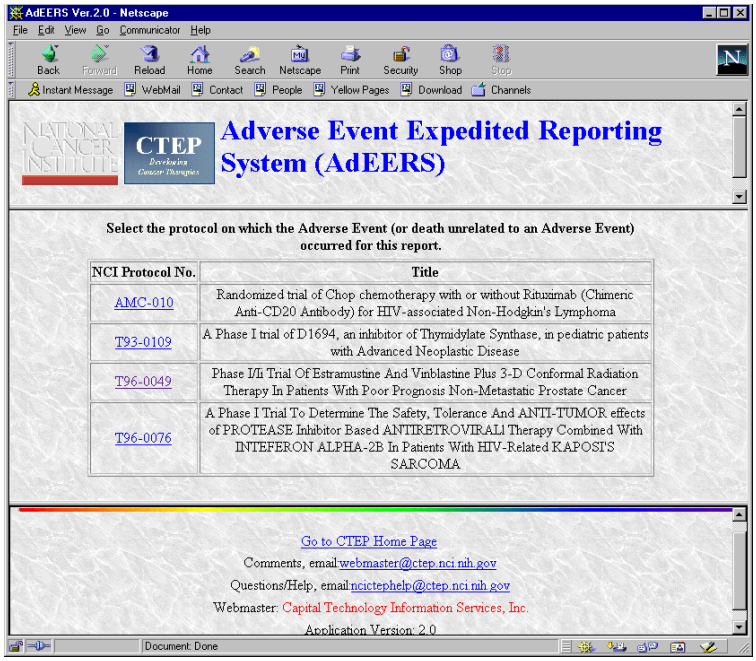

Figure 58 - NCI Protocols Available for Submission of Adverse Event Reports Screen

2. Click the NCI Protocol Number for which a report is to be copied.

   The **Assess Whether or Not an Adverse Event(s) is Reportable** screen appears, as shown in Figure 59. The following options are available in the left frame of this screen:

   If death is unrelated to an AE, click here - Select to assess AE(s) where a death was unrelated to the AE.

   ReQuery - Select to view a list of AE(s) entered for assessment.

   New Adverse Event - Select to begin the check to determine if an AE is reportable.

   Assessment Results - Select to view the results of a **New Adverse Event** check.

   Proceed with Report - Select to bypass the checks to determine if an AE is reportable.

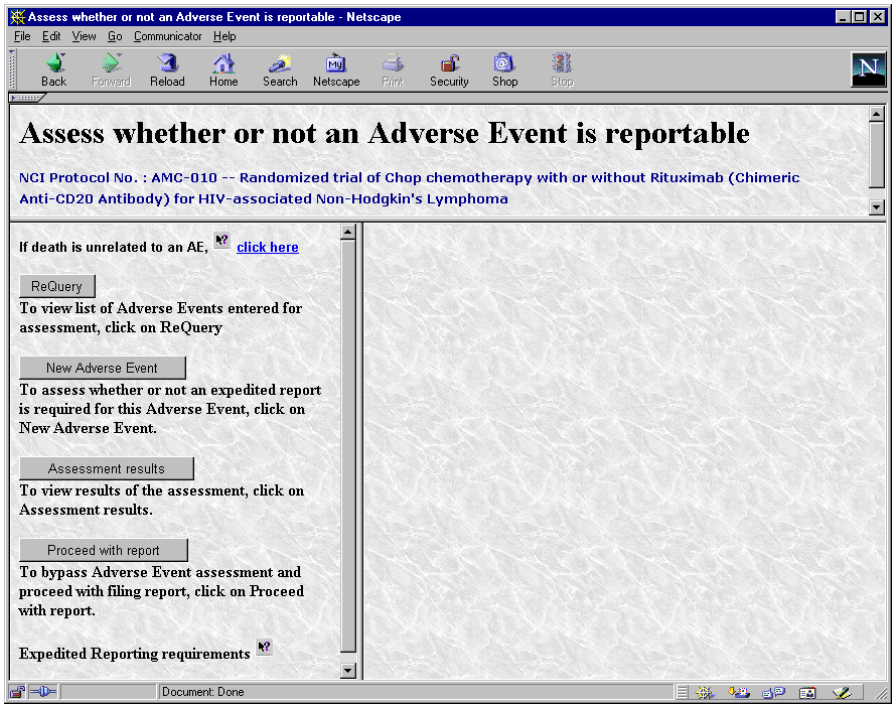

Figure 59 - Assess Whether or Not an Adverse Event is Reportable Screen

3. Click **Proceed with report** to continue with the copying of the report.

   The **Expedited Reports** screen appears, as shown in Figure 60, with a listing of reports that are pending for the selected protocol.

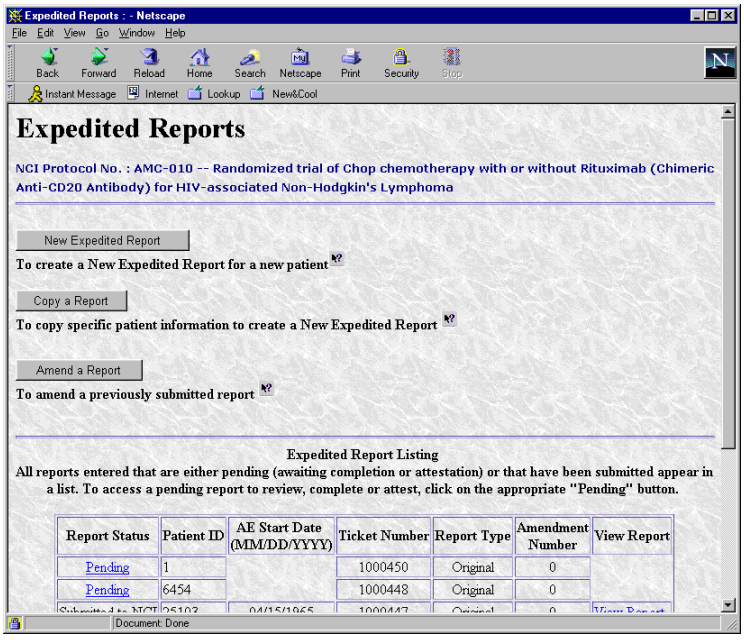

Figure 60 - Expedited Reports Screen

4. Click **Copy a Report**.

The **Copy Report** screen appears. **Copy Report** is selected to copy specific patient information from a submitted report to create a new Expedited Report.

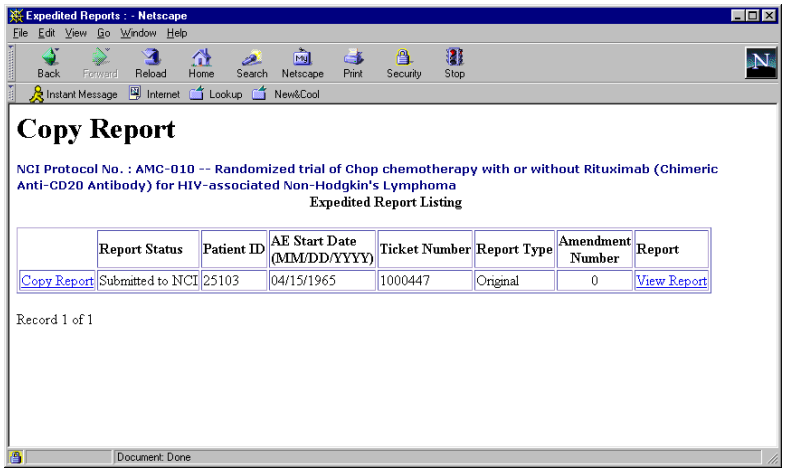

Figure 61 - Copy Report Screen

5. Click **Copy Report** for the report to be copied.

   At this point, the **Sections of Report** Screen is displayed. Select **Next** to view the AdEERS Menu.

   Refer to sections Enter Reporter Information through Enter Additional Information on pages 17 through 43 to access the sections of the report to be copied.

Amend an Expedited Report

This process allows the user to amend a previously submitted report. The original report will be accessed and used to create a new report. Information may then be modified prior to submitting the new report. The amended report will be linked to the ticket number for the original report and will contain account information associated with the user making the amendment. This example documents the procedure to amend an Expedited Report that has been submitted to NCI. All sections are copied when this option is selected. The **Amend Report** option is only available from the **Expedited Report** screen.

1. Select **Submit an Expedited Report for an NCI Sponsored Investigational Agent**.

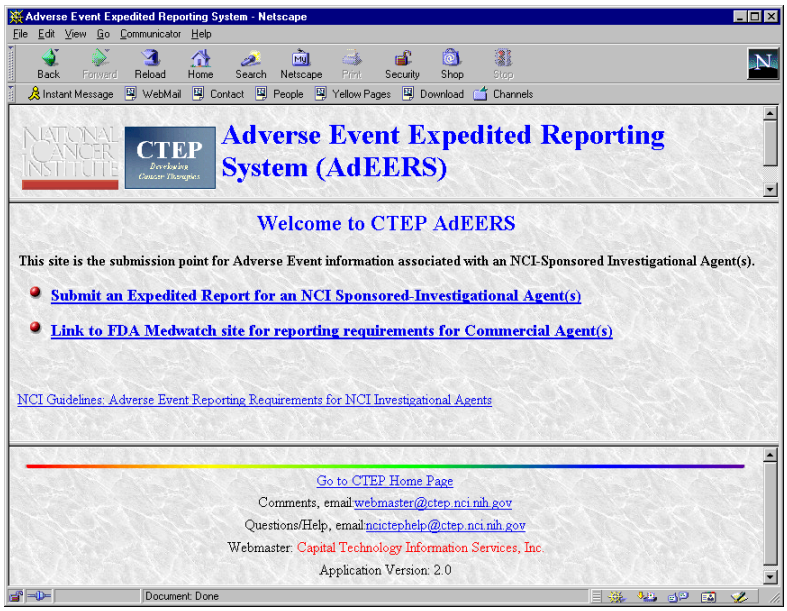

Figure 62 - AdEERS Main Menu - Adverse Event Expedited Reporting System (AdEERS)

A screen appears with a table of protocols available for selection, as shown in Figure 63. This table shows the NCI Protocol Numbers and the title of the protocols.

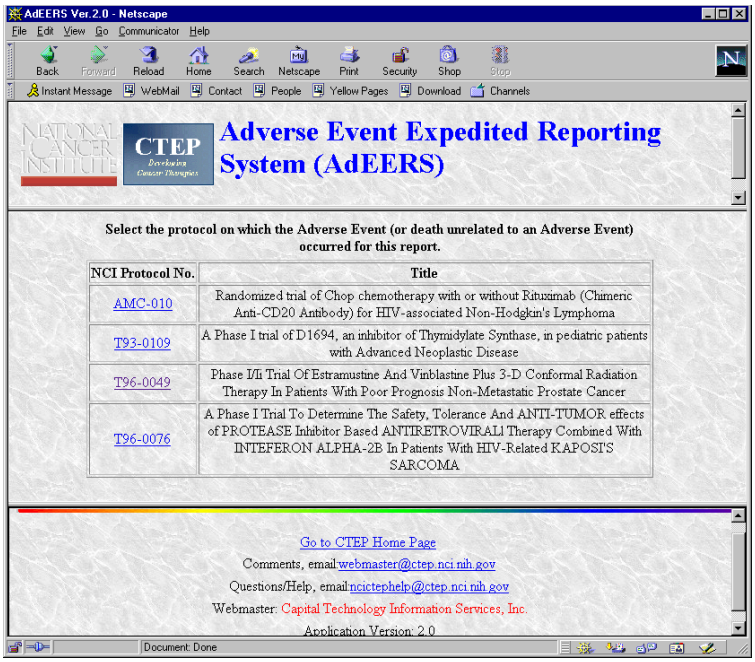

Figure 63 - NCI Protocols Available for Submission of Adverse Event Reports Screen

2. Click the NCI Protocol Number for which a report is to be amended.

   The **Assess Whether or Not an Adverse Event(s) is Reportable** screen appears, as shown in Figure 64. The following options are available in the left frame of this screen:

   If death is unrelated to an AE, click here - Select to assess AE(s) where a death was unrelated to the AE.

ReQuery - Select to view a list of AE(s) entered for assessment.

New Adverse Event - Select to begin the check to determine if an AE is reportable.

Assessment Results - Select to view the results of a **New Adverse Event** check.

Proceed with Report - Select to bypass the checks to determine if an AE is reportable.

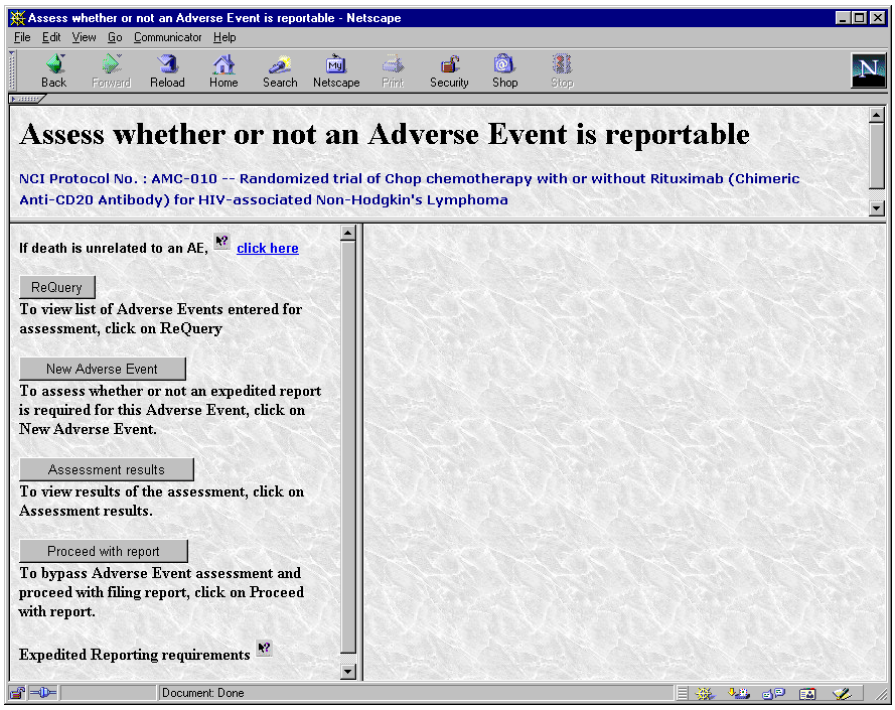

Figure 64 - Assess Whether or Not an Adverse Event is Reportable Screen

3. Click **Proceed with report** to continue with amending the report.

The **Expedited Reports** screen appears with a listing of all reports that are pending for the selected protocol. Submitted reports are grayed out.

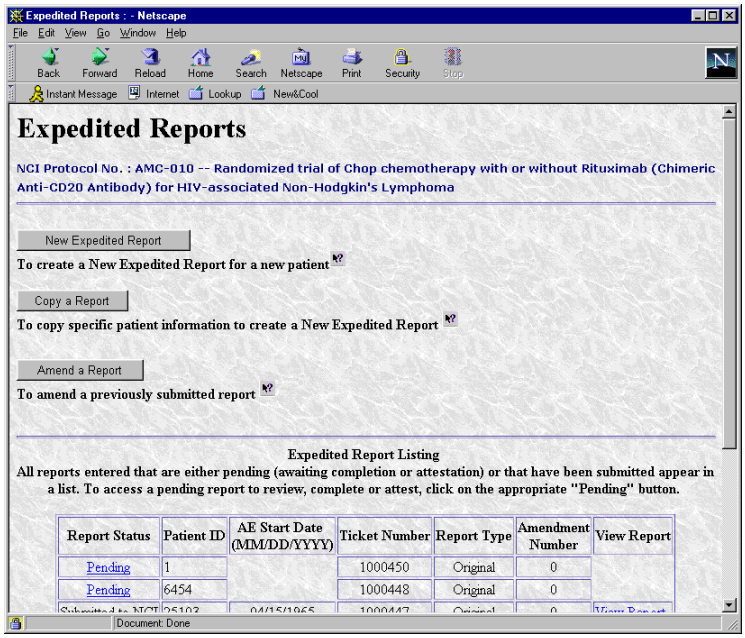

Figure 65 - Expedited Reports Screen

4. Click **Amend a Report**.

   The **Amend Report** screen appears. **Amend Report** is selected to amend the report and **View Report** is selected to view the report.

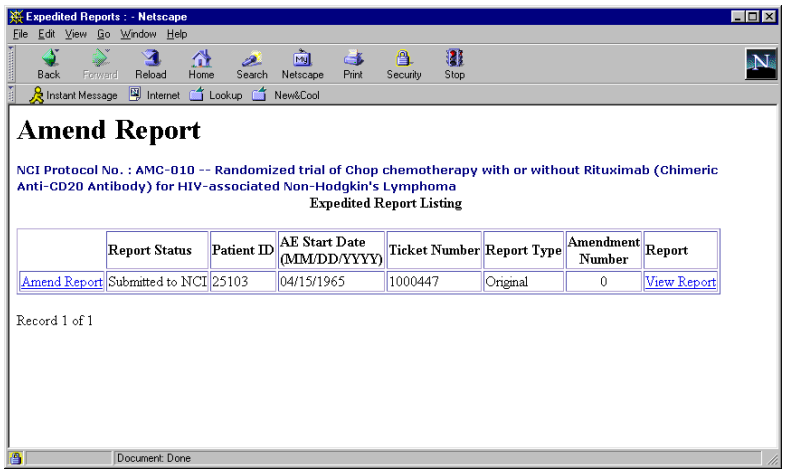

Figure 66 - Amend Report Screen

5. Click **Amend Report** for the report to be amended.

   At this point, the **Sections of Report** Screen is displayed. Select **Next** to view the AdEERS Menu.

   Refer to sections Enter Reporter Information through Enter Additional Information on pages 17 through 43 to access the sections of the report to be amended.

Prepare a Report if a Death is Unrelated to an AE

AdEERS determines the reporting requirement for an individual AE through a series of screens on which the user provides specific information about the event. There are four mandatory sections for reporting if a death is unrelated to an AE. They are:

- Course Information,
- Protocol Agents,
- Patient Information, and
- Documentation of Events.

However, if data for other sections are available and could provide valuable information to assess the death, completion of those sections is required.

1. Select **Submit an Expedited Report for an NCI Sponsored Investigational Agent**, as shown in Figure 67.

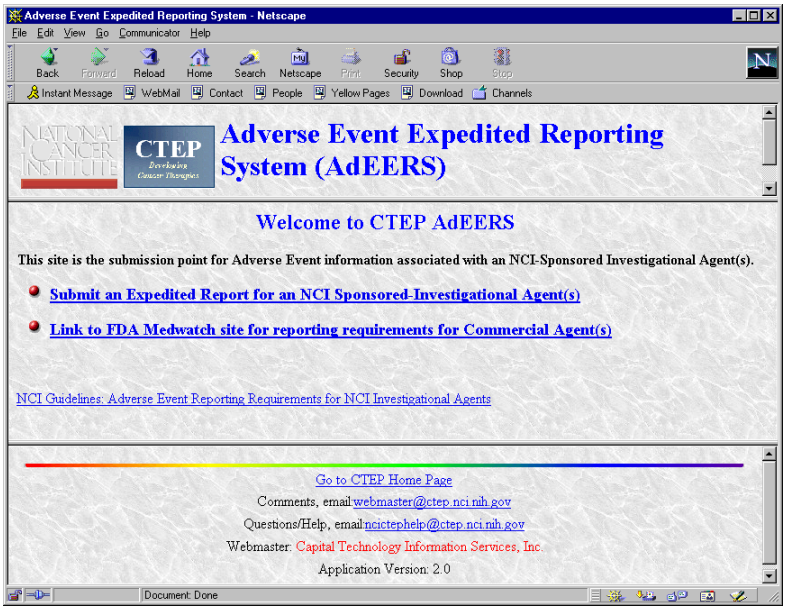

Figure 67 - AdEERS Main Menu - Adverse Event Expedited Reporting System (AdEERS)

A screen appears with a table of protocol(s), specific to the username, available for selection. This table shows the NCI Protocol Numbers and the title of the protocol(s).

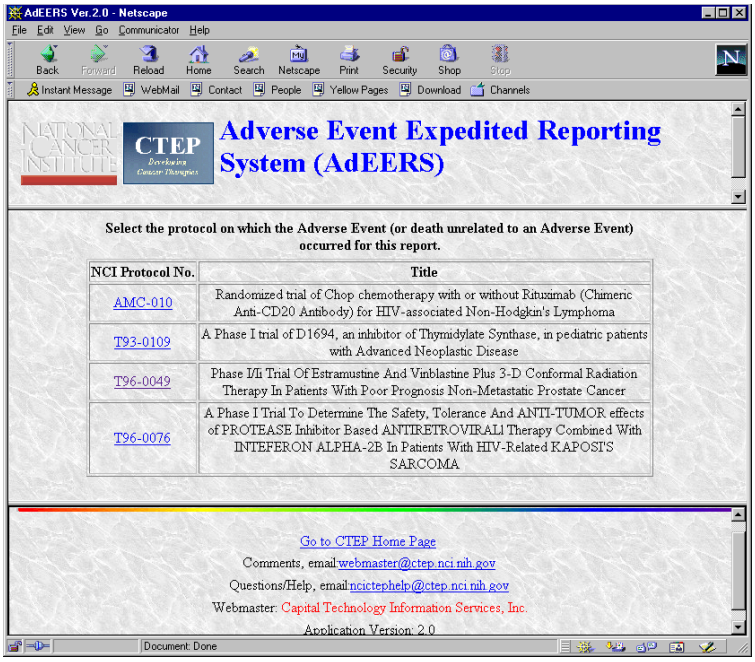

Figure 68 - NCI Protocols Available for Submission of Adverse Event Reports Screen

2. Click the NCI Protocol Number for which an event is to be assessed.

   The **Assess whether or not an Adverse Event is reportable** screen appears. The following options are available in the left frame of this screen:

   If death is unrelated to an AE, click here - Select to assess AE(s) where a death was unrelated to the AE.

   ReQuery - Select to view a list of AE(s) entered for assessment.

   New Adverse Event - Select to begin the check to determine if an AE is reportable.

   Assessment Results - Select to view the results of a **New Adverse Event** check.

   Proceed with Report - Select to bypass the checks to determine if an AE is reportable.

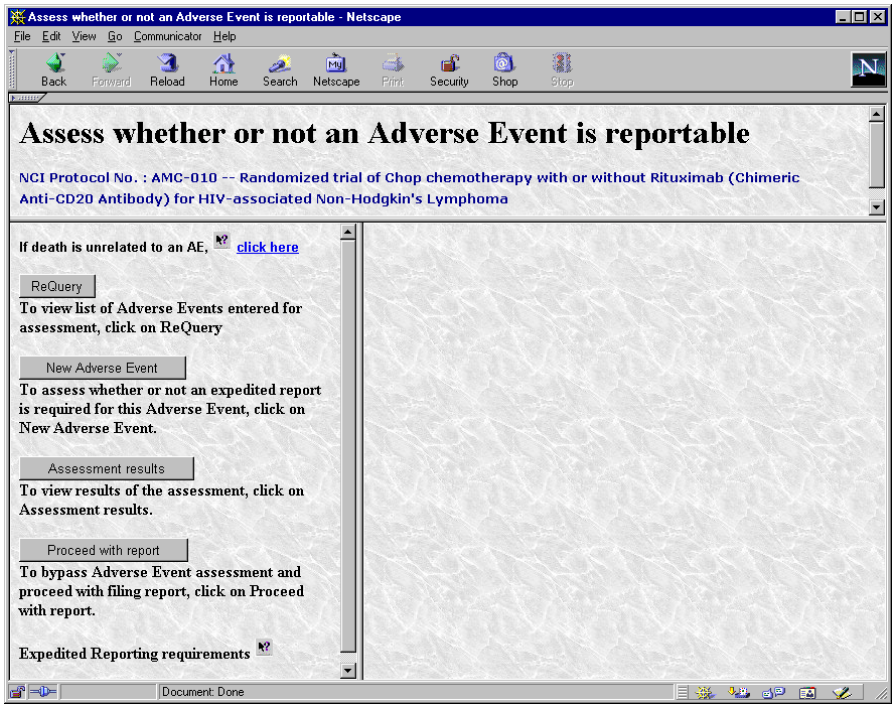

Figure 69 - Assess Whether or Not an Adverse Event is Reportable Screen

3. Click **click here** in the **If death is unrelated to an AE,** area.

   The **Expedited Reports** screen appears, as shown in Figure 70. The following options are available on this screen:

   New Expedited Report - Select to create a new Expedited Report.

   Copy a Report - Select to copy specific patient information from a submitted report to create a new Expedited Report.

   Amend a Report - Select to amend an existing Expedited Report.

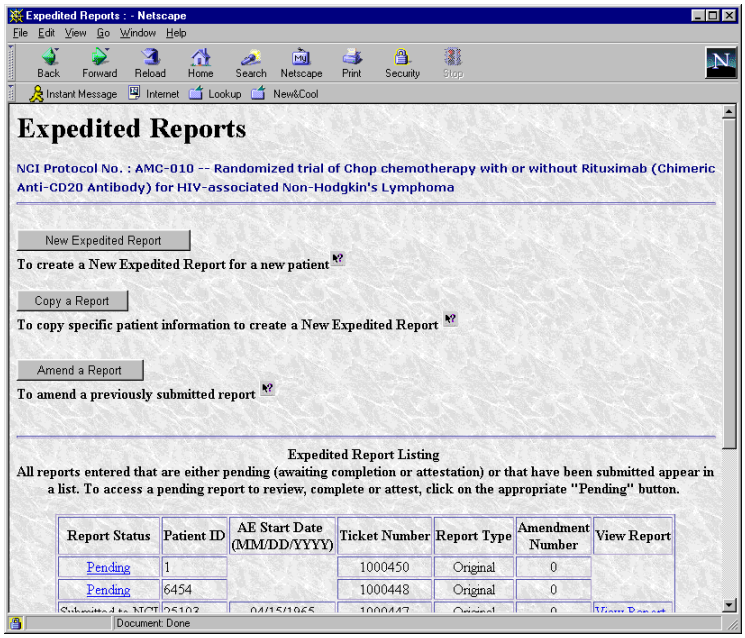

Figure 70 - Expedited Reports Screen

4. Click **New Expedited Report**.

   The **Reporter Information** screen appears. The PI information is pre-populated based upon the user account entering the AE information.

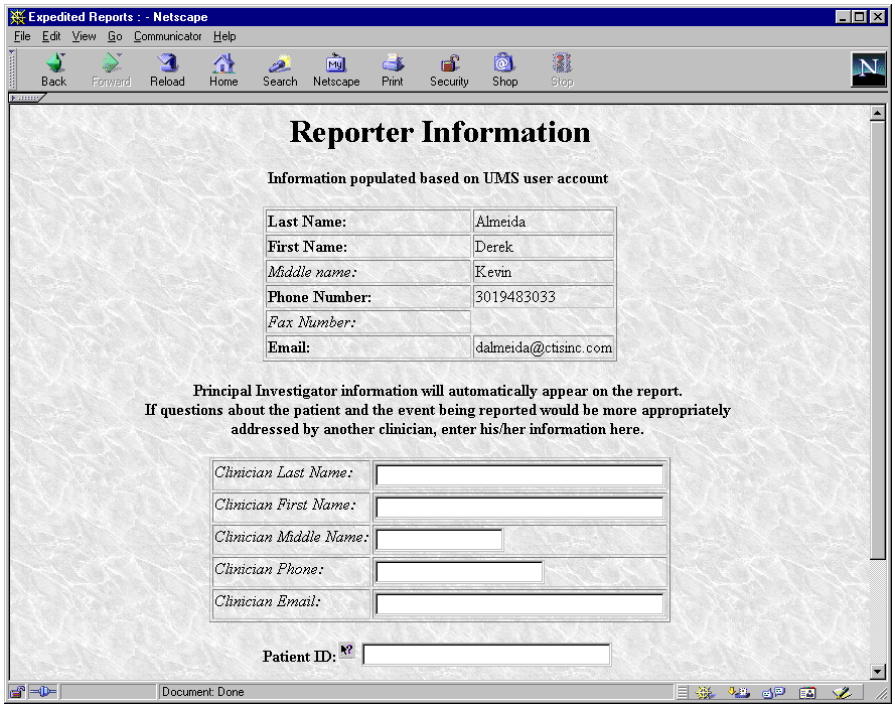

Figure 71 - Reporter Information Screen

5. Complete the following fields if the questions about the patient and event being reported would be more appropriately addressed by another clinician:

   Clinician Last Name:

   Clinician First Name:

   Clinician Middle Name:

   Clinician Phone:

   Clinician Email:

6. Enter the patient ID in the **Patient ID:** field.
7. Click **Save**.

The **Sections of Report** screen is displayed, as shown in Figure 72.

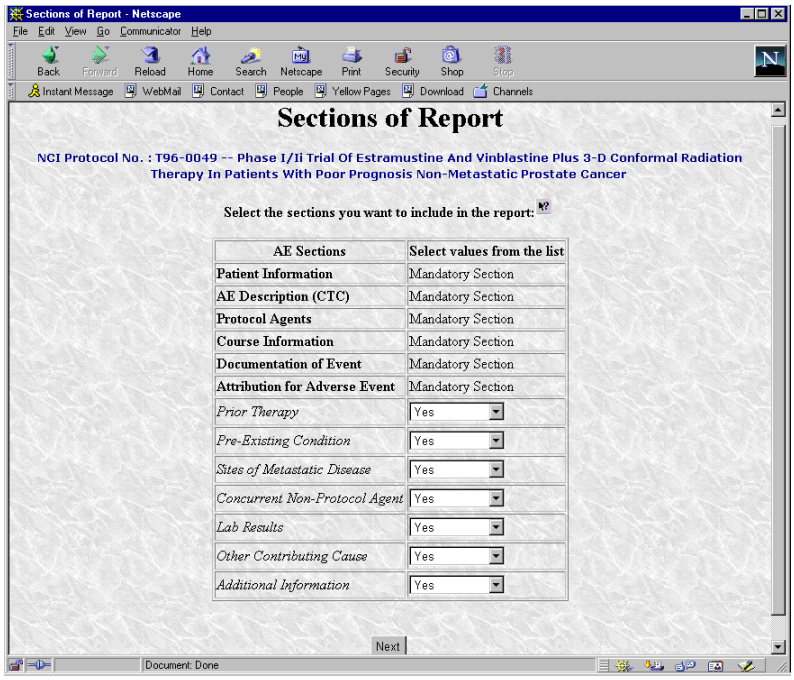

Figure 72 - Sections of Report Screen

8. Click applicable down arrow to select **No** for any **AE Sections** that are not applicable for this report.
9. Click **Next**.

The AdEERS Menu appears, as shown in Figure 73. The commands listed are used to create a new AE Report, or to modify a pending AE Report, and submit the report to NCI. Mandatory and selected AE sections from the **Sections of Report** screen are included as commands in this menu. The menu commands may be chosen in any order. This procedure, as documented here, simply follows the top to bottom structure of the menu.

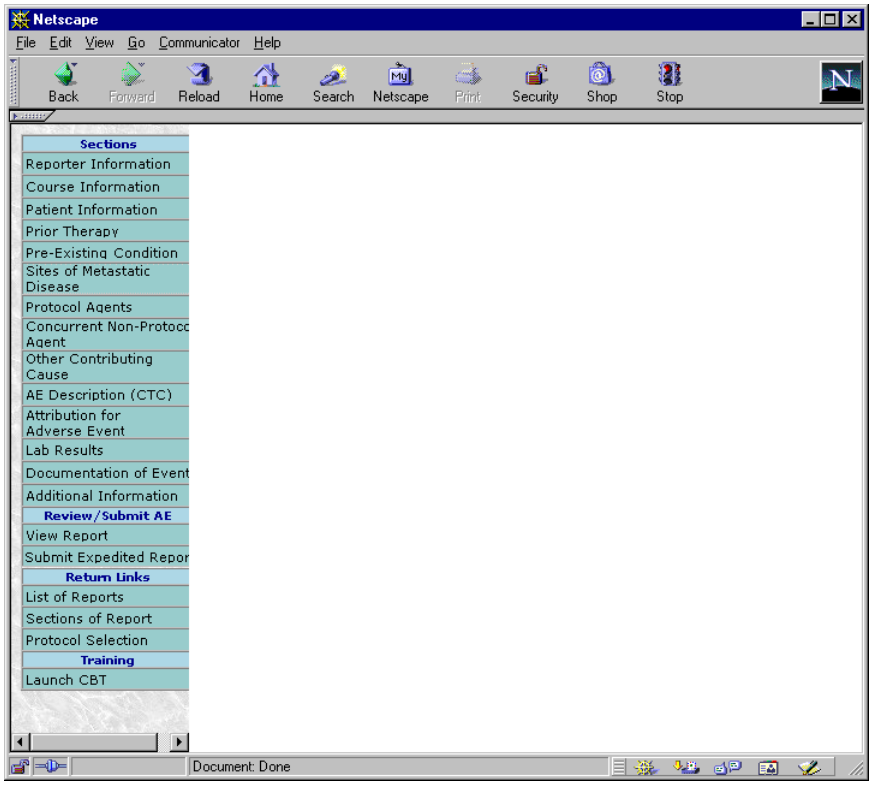

Figure 73 - AdEERS Menu

10. Click **Save**.

    At this point, refer to Sections Enter Reporter Information through Enter Additional Information to complete the report submission. When **Documentation of Event** is selected, a new field, **Cause of Death:** appears, as shown in Figure 74. This field will not appear unless reporting if a death unrelated to an AE is occurring.

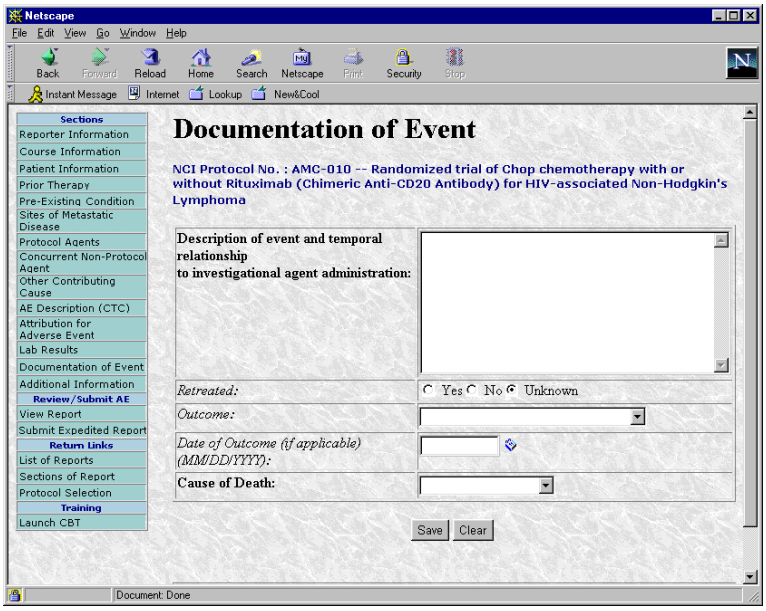

Figure 74 - Documentation of Event Screen

The options available under **Cause of Death** are: **Accident**, **Homicide**, **Progressive Disease**, **Sudden Death**, **Suicide**, and **Unknown**.

View Expedited Report

An Expedited Report may be viewed at any time prior to submission by following the steps in this section. Ensure that all required information has been entered. Perform the necessary steps in section

Enter Data for an Expedited Report for a New Patient**,** beginning on page 17, prior to performing this procedure. A report may also be viewed by clicking the **View Report** link contained on other screens in AdEERS.

1. Click **Expedited Report** under **Review/Submit AE** on the AdEERS Menu.

   The **AE Report** appears, as shown in Figure 75. The scroll bar is used to review the report.

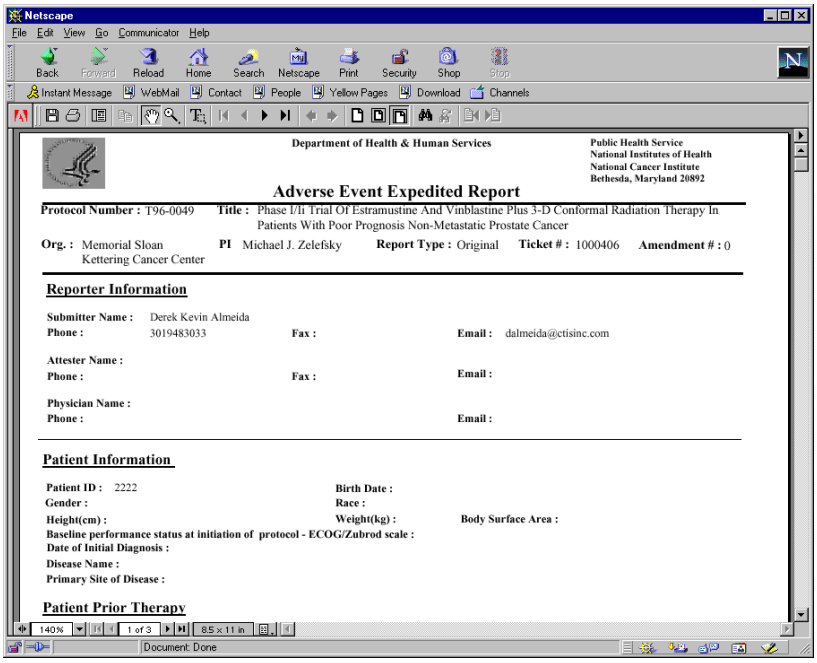

Figure 75 - Adverse Event Report

Submit Expedited Report

An Expedited Report may be submitted at any time once all required sections are completed. Only individuals with User Management System (UMS) attestation privileges will have access to this section of the report. Reports listed on this screen are all "Pending" awaiting either completion or attestation. Reports may be printed and filed locally. The ticket number appears on the printed report, facilitating retrieval of the report in the AdEERS system in the future. Submitted reports, selected by ticket number, can be accessed in AdEERS for amending or copying. If the report selected to be submitted is incomplete, a message appears with all the uncompleted sections.

1. Click **Submit Expedited Report** under **Review/Submit AE** on the AdEERS Menu.

   The **Submit Expedited Report** screen appears, as shown in Figure 76.

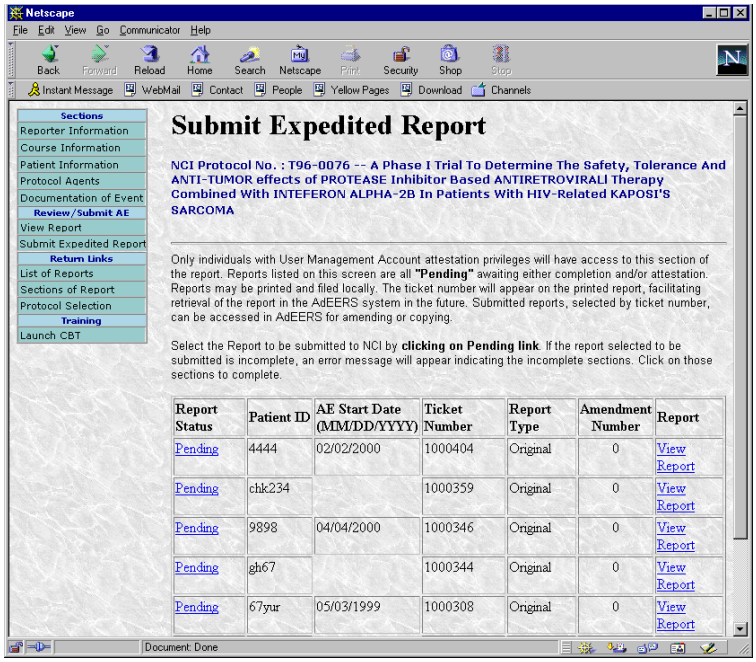

Figure 76 - Submit Expedited Report Screen

2. Click the **Pending** link for the report(s) to be submitted.

   The **Attester Information** screen appears, as shown in Figure 77.

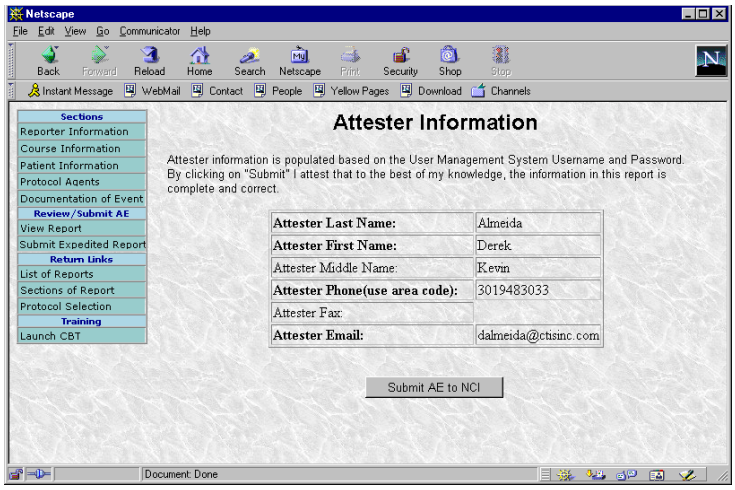

Figure 77 - Attester Information Screen

3. Click **Submit AE to NCI** to submit the report to NCI.

   "Success" appears.

View List of Reports

A list of reports may be viewed at any time by following the steps in this section. From this list a new Expedited Report may be created, an Expedited Report may be copied, or an existing Expedited Report may be amended.

1. Click **List of Reports** under **Return Links** on the AdEERS Menu.

   The **Expedited Reports** screen appears, as shown in Figure 78.

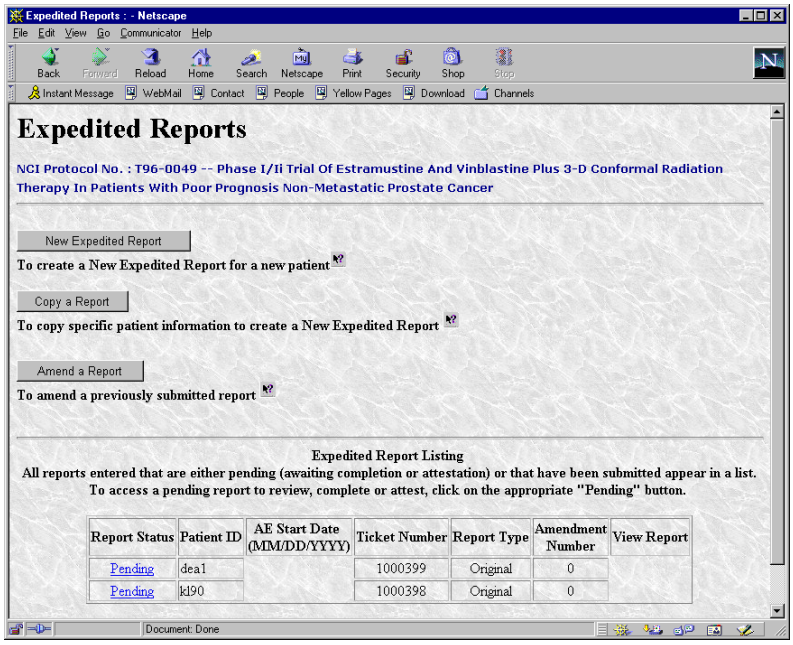

Figure 78 - Expedited Reports Screen

New Expedited Report is selected to create a new AE Report for a new patient. **Copy a Report** is selected to copy specific patient information from a submitted report to create a new Expedited Report. **Amend a Report** is selected to amend a previously submitted AE Report.

View Sections of Report

The sections of a report may be viewed at any time by following the steps in this section. Sections previously not selected to be a part of the report may be selected and completed at this time.

1. Click **Sections of Report** under **Return Links** on the AdEERS Menu.

The **Sections of Report** screen appears, as shown in Figure 79. Sections in **bold** are mandatory sections for the report. Sections in *italics* are optional, but are selected by default.

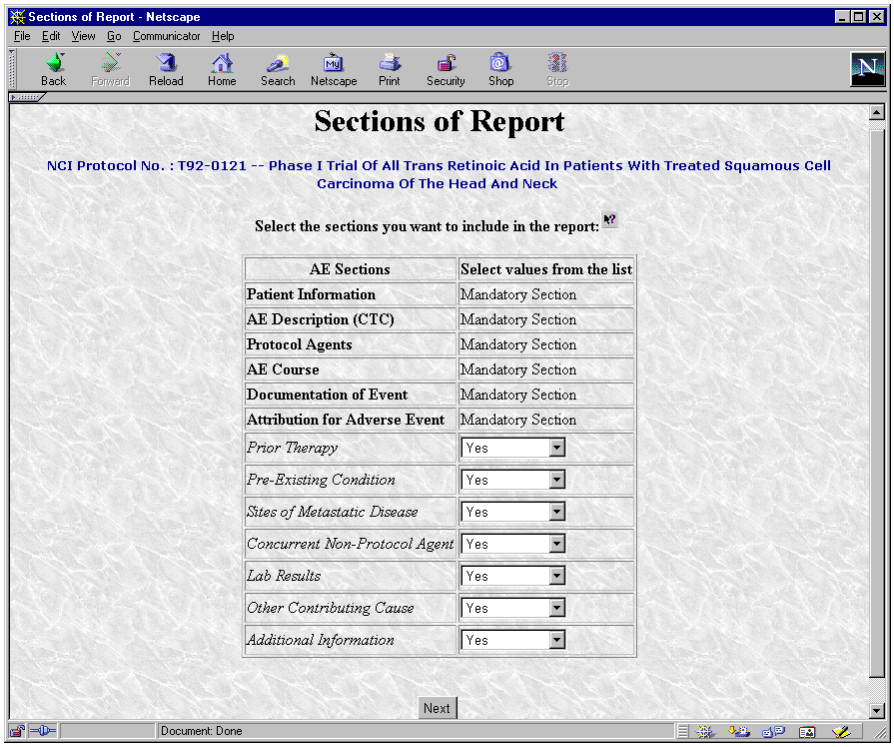

Figure 79 - Sections of Report Screen

View Protocol Selection

The Protocol Selection may be viewed at any time by following the steps in this section.

1. Click **Protocol Selection** under **Return Links** on the AdEERS Menu.

   A screen appears, as shown in Figure 80, with a table of protocol(s), specific for the username. This table shows the NCI Protocol Numbers and the title of the protocol(s).

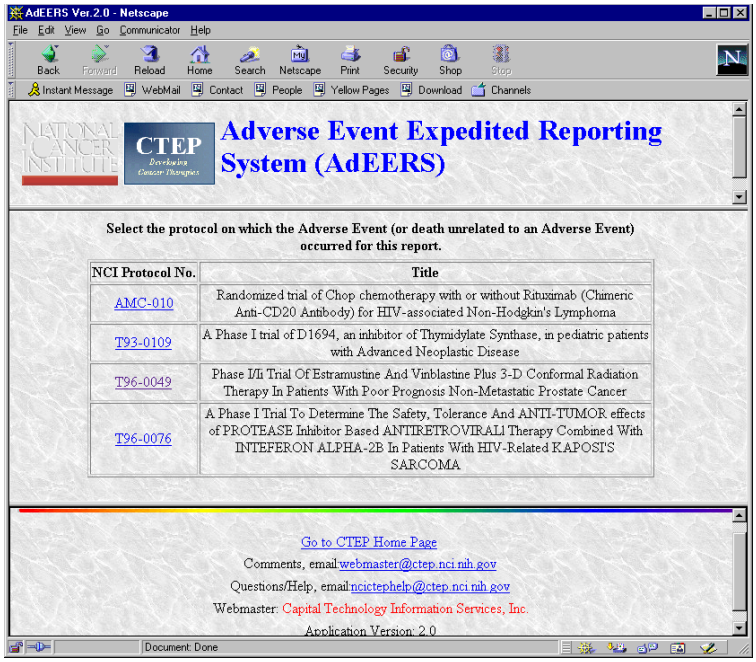

Figure 80 - NCI Protocols Available for Submission of Adverse Event Reports Screen

Submit Adverse Event Report for a Commercial Agent

An Adverse Event Report for a Commercial Agent should only be submitted for any unexpected (not listed in the package label) life-threatening Grade 4 or Grade 5 adverse event with an attribution of Possible, Probable, or Definite. Selection of this option provides a link to assess the event for reportability, and instructions for submitting the report.

1. Click **Link to FDA MedWatch site for reporting requirements for Commercial Agent(s)** on the AdEERS Main Menu.

   The **Adverse Event for Commercial Agent(s)** screen appears, as shown in Figure 81.

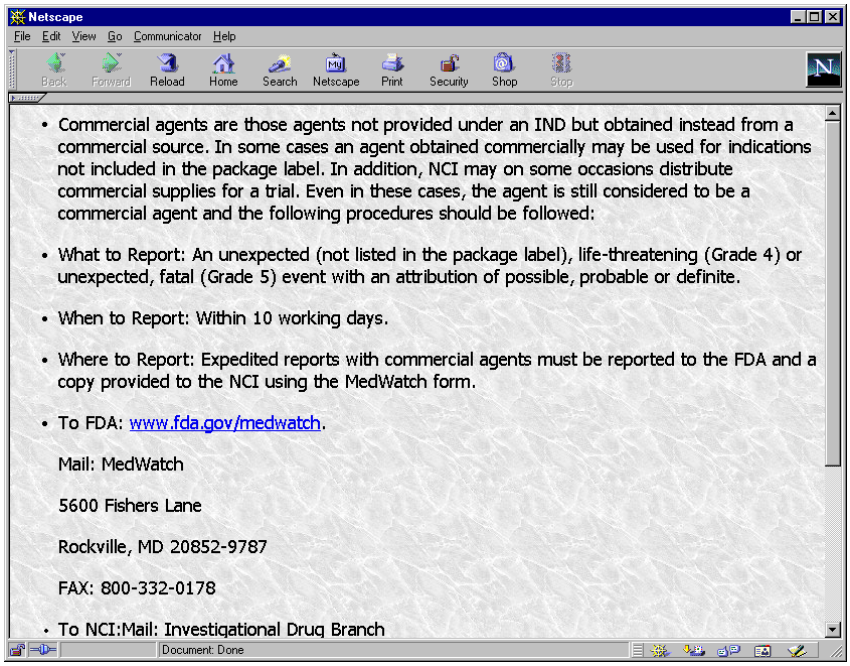

Figure 81 - Adverse Event for Commercial Agent(s) Screen

The FDA MedWatch link on this screen provides instructions for assessing and reporting adverse events for commercial agents. A link is provided at the bottom of the screen to **Return to application**.

Access AdEERS Computer Based Training

AdEERS Computer Based Training (CBT) may be accessed from the AdEERS Menu. This CBT provides step-by-step instructions for using AdEERS as well as comprehensive definitions for data associated with AdEERS.

1. Click **Launch CBT** under **Training** on the AdEERS Menu.

   AdEERS CBT is launched, as shown in Figure 82. Follow the instructions to access this training.

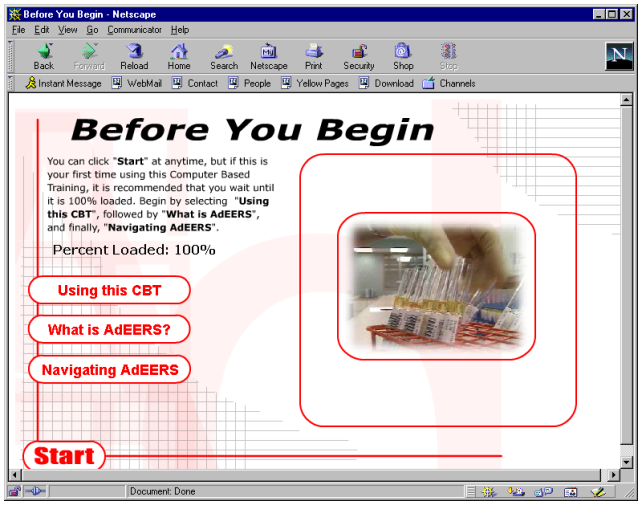

Figure 82 - AdEERS CBT

Glossary of Terms and Definitions

AdEERS	Adverse Event Expedited Reporting System - Web-based computer application used to electronically submit data concerning adverse events experienced with investigational agents supplied by the National Cancer Institute (NCI) Division of Cancer Treatment and Diagnosis (DCTD)
Adverse Event	Any unfavorable or unintended symptom, sign, or disease that may or may not be considered related to the intervention
AE	Adverse Event
Agent	Chemical or biologic entity used for the treatment of cancer
Assessment Results	Results of an AdEERS assessment of whether or not an event requires Expedited Reporting, that was made based upon user entered information
Attribution	The determination of whether an adverse event is related to a medical treatment or procedure
CDUS	Clinical Data Update System
Chemotherapy	Treatment with anticancer agents
Commercial Agent	FDA approved agent available from a commercial source
CTC	Common Toxicity Criteria, Version 2.0 Standard language for reporting Adverse Events
CTEP	Cancer Therapy Evaluation Program
DCTD	Division of Cancer Treatment and Diagnosis
FDA	Food and Drug Administration
Frequency	Frequency with which an agent is administered
Grade	Severity of an adverse event
Investigator	Experienced clinical researcher who prepares a protocol or treatment plan and implements it with patients, and/or a physician who assumes full responsibility for the treatment and evaluation of patients during research protocols and for the integrity of the research data
LOV	List of values
MedDRA	Medical Dictionary for Drug Regulatory Affairs
Metastasis	Transfer of disease from one organ or part of the body to another
NCI	National Cancer Institute
Password	Provided to user by UMS Administrator
Patient	Person participating in a clinical trial
Patient Demographics	Patient information including, but not limited to gender, race, age, height, weight, etc.
Patient ID	Unique identifier assigned to a patient
Phase	Different levels of studies in the clinical development of an agent
Principal Investigator (PI)	Physician who has organizational and fiscal responsibility for the use of Federal funds to conduct a plan of research

Prior Therapy	Describes the therapy received by a patient before the patient's participation in a given clinical trial
Protocol	Outline or plan for use of an investigational procedure or investigational treatment
Route	Method by which the agent is administered
Schedule	Frequency of dose administration
Therapy	Form of intervention
Treatment Assignment	A unique study ARM or dose level utilized to uniformly group patients for separate treatment and/or analysis of the study's primary objective
Treatment Assignment Code	A short description (less than ten characters) of a treatment ARM or dose level
Username	Provided to user by UMS Administrator
UMS	User Management System

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